



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply.

EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division



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April 12, 2000

MEMORANDUM

SUBJECT: DIAZINON. Revised HED Preliminary Human Health Risk Assessment for the Reregistration Eligibility Decision (RED) D262343. PC Code: 057801. List A Case No. 0238.

FROM: Catherine Eiden, Chemist
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TO: Ben Chambliss, Special Review Manager
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This memorandum, the accompanying human health risk assessment and attachments serve as the Revised HED Preliminary Human Health Risk Assessment for the RED for diazinon. This document reflects revisions to the Diazinon Preliminary Risk Assessment (1/11/00) made in response to the registrant's (Novartis) comments made during the Phase I (30-day error correction) of the TRAC pilot process. The attachments include: 1) HED Toxicology Chapter (Attachment I), 2) Report of the Hazard Identification Assessment Review Committee (HIARC) memorandum (9/21/99) (Attachment II), 3) FQPA Safety Factor Recommendations for the Organophosphates (6/9/98) (Attachment III), 4) HED Residue Chemistry Chapter (Attachment IV), 5) the acute and chronic dietary exposure analyses dated 10/18/99 (Attachment V), 6) HED Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Diazinon (11/29/99) (Attachment VI), 7) EFED Drinking Water Resources Assessment (Attachment VII), and 8) Review of Diazinon Incident Reports

(Attachment VIII). These attachments contain the basic information used here to describe the overall exposure and risk estimates associated with the use of diazinon. Cumulative risk assessment, which considers risks from other pesticides which have a common mechanism of toxicity is not addressed in this document.

Under the toxicity sections of this document, revisions have been made in response to the 30-day registrant error correction review.

Under the residue chemistry sections of this document, revisions have been made in response to the 30-day registrant error correction review. HED notes that the following raw agricultural commodities were excluded from the current dietary risk assessments: olives, peanuts, pecans, soybeans, sugarcane, beans, guar, and cowpeas. The registrant voluntarily canceled these uses on December 27, 1996. The Agency is proposing to revoke these tolerances on January 1, 2000. Because secondary residues from milk, eggs, poultry, meat and meat byproducts, except for those of sheep, are not expected, these commodities have been excluded from the dietary analysis. However, secondary residues of diazinon from sheep commodities based on the sheep spray use were included. The registrant (Novartis) has expressed interest in supporting uses on kiwi fruits, and provided the necessary residue data. IR-4 has expressed interest in supporting uses on figs, watercress, and filberts, and provided the necessary residue data for watercress and figs. These four commodities were included in the dietary risk assessment. Also included in the dietary assessments because they have tolerances were: bananas, citrus, coffee, cotton seed meal and oil, dandelion, and sorghum. The HED Residue Chemistry chapter recommends for revocation of these tolerances because the registrant no longer wishes to support these uses. SRRD has requested that these commodities be included in the dietary assessment until it has been determined that no other interested parties wish to support these uses. Once USDA, IR-4, growers groups, and others have had the opportunity to review the document, a decision can be made regarding the tolerances listed for revocation. Although garlic was also included in the dietary assessment, there is no tolerance for this commodity and it will be removed from subsequent revisions to the dietary assessment.

Under occupational/residential sections of this document, revisions have been made in response to the 30-day registrant error correction review. The occupational/residential exposure and risk estimates have been revised to incorporate data included in several new chemical specific exposure studies (MRIDs 40202902, 40466601, 44348801 - 02,-03, -04, & -06, and 44959101) and the registrant's own risk assessments. Specifically, this includes new postapplication occupational assessments for greenhouse uses, and new postapplication residential assessments for turf and indoor crack and crevice uses. Postapplication residential exposures and risk estimates have been calculated using the Revised Standard Operating Procedures for Residential Exposure Assessments Guide, November 1999.

Attachments

HUMAN HEALTH RISK ASSESSMENT

DIAZINON

April 12, 2000

Reregistration Branch 3
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

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ATTACHMENTS:

ATTACHMENT I - HED Toxicology Chapter

ATTACHMENT II - Hazard Identification Assessment Review Committee (HIARC) Report

ATTACHMENT III - FQPA Safety Factor Recommendations for the Organophosphates

ATTACHMENT IV - HED Residue Chemistry Chapter (Revised 4/12/2000)

ATTACHMENT V - Diazinon: Acute and Chronic Dietary Risk Assessment

ATTACHMENT VI - HED Occupational/Residential Exposure Assessment Chapter

ATTACHMENT VII - EFED Memorandum from R. Matzner to C. Eiden (dated 5/11/99)

ATTACHMENT VIII - Review of Diazinon Incident Reports (J. Blondell, 7/2/98)

ATTACHMENT IX - HED Standard Operating Procedure 99.5, "Updated Interim Guidance for Incorporating Drinking Water Exposures into Aggregate Risk Assessments" (8/1/99).

I. EXECUTIVE SUMMARY

Introduction

Diazinon [O,O-diethyl-O-(2-isopropyl-6-methyl-4-pyrimidinyl)phosphorothioate] is a nonsystemic organophosphate insecticide/acaricide registered for use on a variety of terrestrial foods and an aquatic food (watercress), livestock feeds, and livestock (sheep sprays and cattle ear tags). Since August 1986, label statements prohibiting applications to food crops grown in greenhouses have been required. It has registered non-food uses, as well, including: food/feed handling establishments, livestock areas, and indoor/outdoor residential sites. Diazinon has veterinary uses for fleas and ticks. Currently approved veterinary uses are for impregnating pet collars with diazinon. It is also an ingredient in pest strips. It is available in dust, granules, seed dressings, wettable powders, and emulsifiable solution formulations. It can be applied foliarly or as a soil treatment using ground or aerial equipment followed by incorporation in most uses. Based on available usage information, for 1987 through 1997, total annual domestic usage of diazinon is approximately 6 million pounds active ingredient. More recent information places 1999 diazinon sales at 13.5 million pounds of active ingredient. Most of this is allocated to outdoor residential uses, lawn care operators, and pest control operators. States with significant usage include California, Texas, and Florida.

This document contains the results of several human health risk assessments for diazinon based on its current use patterns. All of the risk assessments included in this document were based on a common toxicological endpoint (cholinesterase inhibition) observed following oral, dermal, and inhalation exposures. For the purposes of the risk assessments conducted here, the toxicity of diazinon's oxon and hydroxy diazinon (metabolites) will be considered equivalent to the parent compound.

The general public (nonoccupational exposures) is potentially exposed to diazinon through food, drinking water, and residential uses (home, garden, and pet uses). Diazinon has a wide variety of homeowner uses including lawn treatments, spot treatments, and indoor crack and crevice treatments. Diazinon is applied outdoors by many methods including spray equipment, and granular spreaders. Registered homeowner uses of diazinon may result in short-term dermal, inhalation (any time period), and short-term, inadvertent, oral hand-to-mouth residential exposures. Aggregate risk assessments for non-occupational exposures to diazinon have been conducted for short-term exposures.

The acute aggregate risk assessment examines 1-day exposures to diazinon in food and drinking water. The short-term aggregate risk assessment consists of average exposures to diazinon in food and drinking water, and exposures of a few days duration as a result of residential uses. The chronic aggregate risk assessment examines long-term average exposures to diazinon in food and in drinking water. There are no chronic residential exposure scenarios.

Risk assessments for occupational uses of diazinon include: short-, intermediate-, and long-term dermal and inhalation exposures. Occupational workers are potentially exposed to diazinon from a

multitude of application techniques and multiple formulations. Diazinon treatments include: aerial applications, airblast, groundboom, tractor and push-type granular spreaders, and handled spray equipment.

Occupational dermal exposures of a short duration (1 to 7 days) and of an intermediate duration (7 days to several weeks) may occur. There are some potential long-term occupational exposures expected to occur from the registered uses of diazinon. However, risk estimates for these scenarios are adequately addressed by risk estimates for intermediate-term exposure scenarios because the intermediate- and chronic-term risk assessments use the same toxicological endpoint. Postapplication worker exposure may occur dermally, but not through inhalation.

Diazinon is one of the leading causes of acute reactions to insecticide use reported as poisoning incidents in the United States. This finding is based largely on an examination of Poison Control Center reports. Much of the frequency of reported incidents for diazinon is accounted for by the widespread use of this chemical inside and outside the home. Not counting synergists, diazinon was the fifth most common insecticide found in U.S. homes in a survey conducted by EPA in 1990 (Whitmore et al. 1992). Generally, the rate of poisoning for diazinon does not differ greatly from that for other cholinesterase-inhibiting insecticides. In California the rates of poisoning per thousand applications for diazinon were very close to the median value for 29 selected insecticides. Similarly in the Poison Control Center data the ratios of symptomatic cases to measures of home use (number of containers or applications) for diazinon was close to the median for the 29 selected insecticides.

Hazard Assessment

The toxicology profile demonstrates that diazinon, like other organophosphate pesticides, has anticholinesterase activity in various species including hens, mice, rats, rabbits, and dogs. Clinical signs of toxicity observed in laboratory animals following an acute (single) exposure are consistent with cholinesterase inhibition and include: tremors, convulsions, salivation, and dyspnea (labored breathing). Inhibition of plasma, erythrocyte and/or brain cholinesterase (ChE) activity occurs by all routes (oral, dermal, and inhalation) and for all durations of exposure. Diazinon did not induce organophosphate delayed neuropathy (OPIDN) in hens. No histopathological lesions of the nervous system were seen in either the acute or subchronic neurotoxicity studies. In subchronic and chronic toxicity studies conducted in mice, rats and dogs, systemic toxicity was manifested as cholinergic signs, decreases in body weight and body weight gains. Diazinon is classified as a "not likely human carcinogen" based on the lack of evidence of carcinogenicity in mice and rats when tested at doses that were adequate to assess the carcinogenic potential of this organophosphate. Diazinon was shown to be non-mutagenic following both *in vivo* and *in vitro* mutagenicity assays. Prenatal developmental toxicity studies in rats and rabbits provided no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure. In the two-generation reproductive toxicity study, there was no evidence of increased susceptibility in the offspring as compared to parental animals. In the prenatal developmental toxicity studies, no developmental toxicity was seen at the highest dose tested, and in the two-generation reproductive toxicity study, effects in the offspring were observed only at a dose that caused

parental toxicity. There was no evidence of abnormalities in the development of the fetal nervous system in these studies. Metabolism studies in rats showed that most of the administered diazinon is degraded and/or eliminated within 24 hours postdosing, and does not accumulate in tissues. Diazinon is metabolized in rats through cleavage at the ester linkage resulting in the liberation of the pyrimidinyl group that is oxidized and excreted. There were no major sex- or dose-related differences in the disposition or metabolism of diazinon.

For diazinon, the 10x Food Quality Protection Act (FQPA) safety factor, for the protection of infants and children (as required by the Food Quality Protection Act of 1996), was reduced to 1x based on the: 1) completeness of the toxicology database; 2) lack of evidence of increased susceptibility following pre-, and post-natal exposures; and 3) the use of adequate data (actual, surrogate and/or modeling outputs) to satisfactorily assess dietary and non-dietary exposures. Additionally, there was no evidence for requiring a developmental neurotoxicity study. However, the Agency, recently, has issued a Data-Call-In notice for a developmental neurotoxicity study for all organophosphates, which includes diazinon. As per current policy, a Reference Dose (RfD) modified by an FQPA safety factor is referred to as a Population Adjusted Dose (PAD). Because the FQPA safety factor was reduced to 1x, the acute and chronic RfDs are equal to the acute and chronic PADs, respectively.

For the acute dietary exposure and risk assessment, the dose selected was the No Observed Adverse Effect Level (NOAEL) of 0.25 mg/kg/day based on plasma cholinesterase inhibition at the Lowest Observed Adverse Effect Level (LOAEL) of 2.5 mg/kg/day established in an acute neurotoxicity study in rats. An Uncertainty Factor (UF) of 100 was applied to the NOAEL to account for intra-species extrapolation (10x) and inter-species variation (10x). The resultant acute RfD of 0.0025 mg/kg/day is equivalent to the acute PAD.

For the chronic dietary exposure risk assessment, the dose selected was the NOAEL of 0.02 mg/kg/day based on a weight of evidence of plasma cholinesterase inhibition (red blood cell and/or brain inhibition at higher doses) observed in a four week, subchronic and chronic (oral) studies in rats and dogs. An Uncertainty Factor (UF) of 100 was applied to the NOAEL selected to account for intra-species extrapolation (10x) and inter-species variation (10x). The resultant chronic RfD of 0.0002 mg/kg/day is equivalent to the chronic PAD.

For the short-, intermediate, and long-term dermal exposure risk assessments oral NOAELs were selected because of the lack of a dermal toxicity study in the appropriate species (i.e., rats). The dermal toxicity study in rabbits was deemed unsuitable for use in dermal risk assessments, because of unique physiological and biochemical characteristics of rabbits. Because of these unique characteristics, results from dermally-dosed rabbits have the potential to underestimate the toxic effects of diazinon in other species via the dermal route. A 100% dermal absorption factor was applied to all dermal risk assessments for the purposes of route-to-route extrapolation. Results (mortality) seen following oral and dermal exposure at comparable doses in acute toxicity studies using rabbits support a 100% dermal absorption factor. HED acknowledges that there may be differences in dermal penetration versus dermal absorption. An acceptable dermal absorption

study would reduce uncertainties regarding the dermal absorption of diazinon.

Short-term dermal exposure and risk assessments are based on the oral NOAEL of 0.25 mg/kg/day based on plasma cholinesterase inhibition established in the acute oral neurotoxicity study in rats (the same toxicity endpoint used for acute dietary risk assessment). The intermediate-term and long-term dermal exposure risk assessments are based on the oral NOAEL of 0.02 mg/kg/day based on plasma cholinesterase inhibition seen in oral studies in rats and dogs (the same endpoint used for the chronic dietary assessment). A Margin of Exposure (MOE) of 100 or greater does not exceed HED's level of concern for all dermal exposure scenarios (i.e., short-, intermediate-, and long-term),

For inhalation exposure (short-, intermediate-, and long-term), the dose selected was a LOAEL of 0.026 mg/kg/day (0.1 ug/L) based on inhibition of plasma cholinesterase established in a 21-day inhalation toxicity study in rats. A MOE of 300 or greater does not exceed HED's level of concern for inhalation exposure risk assessments, which includes the conventional 100x, and an additional 3x uncertainty factor for the use of a LOAEL (i.e., a NOAEL was not established in the critical study). In the case of inhalation exposures, a 100% absorption factor is assumed, therefore, the inhalation dose is equivalent to the oral dose.

Risk Characterization

Dietary Risk Estimate (Food):

The acute dietary exposure analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The exposure analysis was performed using the Dietary Exposure Estimate Model (DEEM™) in a probabilistic mode. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989-1992 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. This analysis is refined in that it uses monitoring data from USDA's Pesticide Data Program (PDP) and FDA Surveillance Monitoring Program to calculate anticipated residues for use in the acute dietary analysis. Data on the percentage of a crop-treated was obtained from the Biological and Economic Analysis Division (BEAD) for all commodities with diazinon tolerances included in the acute dietary assessment.

Risk estimates for acute dietary exposure based on existing uses do not exceed HED's level of concern. Risk estimates for all subgroups analyzed (27) are below 100% of the acute population-adjusted dose (aPAD) at the 99.9th percentile of exposure. Currently, HED expresses acute risk as a percentage of the acute population-adjusted dose ($\% \text{ aPAD} = (\text{exposure} \div \text{aPAD}) \times 100$). An exposure to this chemical relative to the acute dietary PAD of less than or equal to 100% of the aPAD does not exceed HED's level of concern. The acute dietary risk estimates (expressed as a % aPAD) are: for the general U.S. population, 35%; for all infants (less than 1 year old), 28%; and for children (1 to 6 years old), 60%. The most highly exposed subgroup was non-Hispanic/non-white/non-black at 64% of the aPAD. This subgroup represents Asians/Pacific Islanders/American Indians, and Alaskan Natives. Sheep fat and meat have been identified as the

food commodities contributing the most to the risk estimates. The maximum reported residue in fat and meat, respectively, from dermal uses were used in the dietary analyses. These maximum residue values were adjusted for percentage of domestic and imported sheep treated with diazinon using available information on the percentage of sheep treated. Although conservative, these estimates for diazinon residues in sheep commodities were considered to be the best available. Additional information on the percentage of domestic and imported sheep treated with diazinon will allow refinement of the risk estimates. If sheep commodities are removed from the acute dietary analysis, risk estimates for all subgroups are below 50% of the aPAD. Additional information on the percentage of imported crops treated with diazinon may also improve the acute risk estimates.

The chronic dietary exposure analysis estimates the average exposure for the overall U.S. population and certain subgroups over a lifetime. The exposure analysis was performed using the Dietary Exposure Estimate Model (DEEM™) in a deterministic mode. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989-1992 CSFII and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of diazinon in the commodity supply. This analysis is refined in that it uses monitoring data from USDA's Pesticide Data Program (PDP) and FDA Surveillance Monitoring Program data to calculate anticipated residues for use in the chronic dietary analysis. Data on the percentage of a crop-treated was obtained from the Biological and Economic Analysis Division (BEAD) for all commodities with diazinon tolerances included in the dietary risk assessment.

Risk estimates for chronic dietary exposure from the registered uses of diazinon are well below 100% of the cPAD, and therefore, do not exceed HED's level of concern for any of the 27 subpopulations analyzed. The chronic dietary risk estimates (expressed as a percentage of the chronic population-adjusted dose (cPAD) are: for the general U.S. population, 10%; for non-Hispanic/non-white/non-black, 16%; for all infants (less than 1 year old), 10%; and for children (1 to 6 years old), 13%. This refined analysis used percent crop-treated data and anticipated residues based on USDA PDP and FDA monitoring data, and field trials. Additional information on the percentage of domestic and imported sheep and imported crops treated with diazinon will allow refinement of the chronic risk estimates.

Dietary Risk Estimates (Drinking Water):

Currently, HED uses drinking water levels of comparison (DWLOCs) as a surrogate measure of potential risks associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). A DWLOC may vary with drinking water consumption patterns and body weights for specific subgroups. In the absence of monitoring data on diazinon in drinking water, HED compares estimated peak and average concentrations of a pesticide in surface and ground water from conservative models to DWLOC values for acute and chronic assessments, respectively, in a screening-level assessment to semi-quantitatively estimate risk from exposure through drinking

water. If screening-level model estimates are less than the calculated DWLOC values, there is no drinking water concern. This is considered a preliminary exposure assessment for the purposes of incorporating drinking water exposures into the human health risk assessment. This screening-level assessment has been refined by appropriate and applicable monitoring data when available. This approach is in accordance with "OPP's Interim Approach for Addressing Drinking Water Exposure", S. Johnson, 11/17/97.

Most monitoring efforts to date for diazinon in surface and groundwater have included the parent compound only, and there was no mention of the likelihood of detecting hydroxy diazinon or the diazinon oxon in water in the drinking water assessment (Attachment VII). The HED Metabolism Assessment Review Committee (MARC) concluded that focusing on diazinon, *per se*, in water should be adequate for the purposes of risk assessment. This decision included consideration of the likelihood of occurrence in water of major soil and water metabolites that are toxicologically significant (HED MARC memorandum from D. Hrdy to G. Kramer dated 4/17/98).

Acute Drinking Water Risk Estimates

Concentration estimates for acute exposures to diazinon in *groundwater* based on *model* estimates and *monitoring* data are less than the acute DWLOC values for all subgroups. HED concludes that there is no drinking water concern for acute exposures to diazinon in groundwater-sourced drinking water. Concentration estimates for acute exposures to diazinon in ambient *surface water* based on *monitoring* data are less than the acute DWLOC values for all subpopulations analyzed. However, comparing acute DWLOC values to *model* estimates for concentrations of diazinon in surface water (which are approximately one order of magnitude greater than the concentration estimates from monitoring data) there is a potential concern for infants and children (1 to 6 years old). Therefore, HED cannot conclude that there is no concern for exposures to diazinon in surface-water-sourced drinking water. Given the uncertainty in diazinon concentrations in surface water based on a comparison of the model estimates and monitoring data relative to each other (10x), and therefore, the uncertainty relative to diazinon concentrations in drinking water, HED recommends reassessing the potential acute exposure to diazinon in drinking water once surface water-sourced drinking water monitoring data on diazinon become available for use.

Chronic Drinking Water Risk Estimates

Concentration estimates for chronic exposures to diazinon in *groundwater* based on *model* estimates and *monitoring* data are less than the chronic DWLOC values for all subgroups analyzed. HED concludes that there is no drinking water concern for chronic exposures to diazinon in groundwater-sourced drinking water. Concentration estimates for chronic exposures to diazinon in ambient *surface water* based on monitoring data are less than the chronic DWLOC values for all subgroups. However, comparing chronic DWLOC values to *model* estimates for concentrations of diazinon in surface water (which are approximately one order of magnitude greater than the concentration estimates from monitoring data) there is a potential concern for infants, children (1 to 6), and females 13+ years old. Therefore, HED cannot conclude that there

is no concern for exposures to diazinon in surface-water-sourced drinking water. Given the uncertainty in diazinon concentrations in surface water based on a comparison of the model estimates and monitoring estimates relative to each other (10x), and therefore, the uncertainty relative to diazinon concentrations in drinking water, HED recommends reassessing the potential chronic exposure to diazinon in drinking water once surface-water sourced drinking water monitoring data on diazinon become available for use.

Occupational/Residential Exposure and Risk Estimates:

HED has conducted an assessment for occupational and residential (non-occupational) exposure scenarios resulting from diazinon's registered uses. A margin of exposure (MOE) greater than 100 for short-term, intermediate-term, and long-term dermal occupational and residential exposures to diazinon does not exceed HED's level of concern. For occupational and residential inhalation exposures of any duration, a target MOE of 300 is necessary. The target MOE for non-dietary, oral exposures (for children's hand-to-mouth exposure) is also 100. When target MOEs for multiple exposure pathways differ, but exposures across those pathways must be combined under an aggregate risk assessment, HED uses the Aggregate Risk Index method (ARI method). ARIs greater than 1.0, do not exceed HED's level of concern.

Residential Risk Estimates:

Handler - Residential handler exposure is considered short-term. No chemical specific exposure data were available to estimate handler exposures to diazinon for typical homeowner uses. In the absence of chemical specific exposure data, HED uses the Residential Standard Operating Procedures (SOPs - December 1997). All MOEs are less than 100 for short-term dermal exposures. MOEs for inhalation exposures are less than 300, and exceed HED's level of concern for all residential handler exposure scenarios, except for applying liquids with a paintbrush at minimum and typical application rates (Scenario 1R). Because all short-term dermal risk estimates exceed HED's level of concern (MOEs < 100), aggregating exposures, (dermal plus inhalation), for residential handlers would only result in risk estimates that further exceed HED's level of concern.

Postapplication Dermal and Inhalation Exposure - Postapplication dermal exposures are expected to be short-term. Risk estimates for these potential exposure scenarios indicate that all residential post-application residential exposures lead to risk estimates above HED's level of concern, except for granular turf use scenarios (lawn treatments). Dermal and inhalation exposures from lawn treatments as well as inhalation exposures from crack and crevice treatments were based on chemical-specific data. However, most of the other exposure scenarios had no chemical specific exposure data available to estimate postapplication exposure to diazinon following typical residential uses. HED used the Revised Residential Standard Operating Procedures (SOPs - November 1999), to calculate postapplication residential dermal exposures. The maximum lawn treatment rate and various indoor application rates were used. Adults and toddler exposures were assessed. Toddlers are the most highly exposed subgroup following lawn and indoor crack and

crevice treatments through direct dermal exposures (crawling) and oral exposures (hand-to-mouth).

Lawn Treatments:

The risk estimates for short-term postapplication dermal and inhalation exposures from lawn treatments are based on a diazinon-specific turf transferable residue (TTR) study submitted by the registrant (MRID 44959101). The November 1999 SOPs were also used for defaults.

Adults

For adult postapplication dermal exposures, the MOE based on average residues across all sites for the liquid formulation is 43, and exceeds HED's level of concern. The dermal MOE based on average residues across all sites for the granular formulation is 360. MOEs for adult inhalation exposures based on average residues across all sites are 300 for liquid formulations and 3400 for granular formulations. All granular-formulated postapplication dermal and inhalation exposure scenarios have MOEs greater than 100, and do not exceed HED's level of concern for adults. Combined postapplication dermal and inhalation exposures for adults from granular formulations result in a risk estimate (ARI) of 2.7, which does not exceed HED's level of concern.

Children

For children's postapplication dermal exposures, the MOE based on average residues across all sites for the liquid formulation is 26. The dermal MOE based on average residues across all sites for the granular formulation is 210.

MOEs for the non-dietary oral exposure pathway for children resulting from hand-to-mouth contact are greater than 420 and vary depending on formulation used and site sampled. The MOE based on average residues across all sites for the liquid formulation is 680. The MOE based on average residues across all sites for the granular formulation is 5600. The MOEs for the non-dietary exposure pathway for children resulting from toddler ingestion of grass and granules from diazinon-treated areas was calculated to be 6800 and 260,000, respectively.

MOEs for children's inhalation exposures based on average residues across all sites are 110 for liquid formulations and 1200 for granular formulations.

Combined estimates of risk for dermal, non-dietary, and inhalation exposures after lawn treatments were calculated for exposure scenarios for granular formulations only as those dermal and inhalation exposures individually had MOEs greater than or equal to 100 and 300, respectively. For toddlers, the short-term dermal and non-dietary exposures (from hand-to-mouth, grass and granule ingestion) result in a MOE of 200. For toddlers, the inhalation exposure, results in a MOE of 1200. Total combined toddler exposure risk estimates from dermal, non-dietary, and inhalation exposures result in an ARI equal to 1.3, which does not exceed HED's level of concern.

Indoor Treatments:

The Agency used the chemical-specific data available from MRID 44348801 to estimate inhalation exposure and risk from indoor uses of diazinon. In 1996, the Agency granted a data waiver for indoor residential dermal postapplication exposure data for diazinon. As a result, the submitted data provided information on airborne residues and subsequent inhalation exposures associated with indoor crack and crevice treatment with diazinon, but no data on dermal exposures to diazinon. To assess exposure and estimate risk for short-term postapplication dermal exposures to diazinon in the home, the Agency used the Revised Standard Operating Procedures for Residential Exposure Assessments Guide (November 1999).

Adults

Adult postapplication short-term dermal exposures, based on Residential SOPs (1999) result in MOEs less than 100. For adults, the inhalation exposure, based on chemical-specific data, result in a MOE of 3.2.

Children's postapplication short-term dermal exposures, based on Residential SOPs (1999) result in MOEs less than 100. For children, the inhalation exposure, based on chemical-specific data, results in a MOE of 1.2.

Combined dermal and inhalation exposures were not used to estimate risk because individual dermal or inhalation exposures or both exceed HED's level of concern. HED anticipates that any combination of these exposures will only further exceed HED's level of concern.

Occupational Risk Estimates:

Applicator/Mixer/Loader - HED has concerns regarding occupational exposures and risk estimates for a number of exposure scenarios during application for pesticide handlers. No chemical specific exposure data were available for the exposure assessments for mixer/loader/applicators (handlers). Short-term and intermediate-term dermal and inhalation exposure assessments were made using the Rapid Exposure and Risk Assessment Tool (RERAT) to estimate risk using 27 occupational exposure scenarios for which surrogate exposure data exist. All scenarios used apply to the registered uses of diazinon. The estimated risks consider maximum mitigation, i.e., baseline clothing, additional personal protective equipment (PPE) including a double layer of clothing and gloves, and engineering controls (closed application and mixing systems, and water soluble packets).

Of the 27 occupational exposure scenarios identified, for short-term dermal exposures, 1 scenario using baseline protection, 7 scenarios using additional PPE, and 8 scenarios using engineering controls have dermal MOEs greater than 100. None of the exposure scenarios for mixing/loading with wettable powders have dermal MOEs greater than 100. For intermediate-term dermal exposure, only 1 scenario using engineering controls has risk estimates (MOEs) greater than or equal to 100. For inhalation exposures, 2 scenarios using baseline protection, 16 scenarios using additional PPE, and 14 scenarios using engineering controls have MOEs greater than 300. Once inhalation and dermal exposures are combined using the Aggregate Risk Index (ARI), regardless of

duration, 10 exposure scenarios have ARIs greater than 1.0, and therefore do not exceed HED's level of concern. All remaining exposure scenarios exceed HED's level of concern, because the dermal risk estimates are less than 100. There are some potential long-term occupational exposures associated with the registered uses of diazinon. However, risk estimates for these scenarios are addressed by the intermediate-term risk estimates because the same toxicological endpoint used for the intermediate-term occupational risk assessment is used for the chronic risk assessment.

Postapplication Dermal Exposure - Short- and intermediate-term postapplication dermal exposures are expected as a result of the registered uses of diazinon on field crops. However, registered greenhouse uses are expected to result in both postapplication dermal and inhalation exposures. HED has concerns over short- and intermediate-term postapplication dermal exposures for workers reentering treated fields. For workers reentering greenhouses, combined dermal and inhalation exposures are of concern at the current reentry interval of 12 hours. All postapplication dermal and inhalation exposures from greenhouse activities result in risk estimates that exceed HED's level of concern.

Chemical-specific dislodgeable foliar residue (DFR) data are available for tree crops (oranges) and cabbage. Data on citrus were used to estimate post-application exposure for tree crops, and once adjusted for differences in application rate, they were used to estimate post-application exposures for grapes.

For tree crops, based on the maximum application rate (3 lb ai/A), intermediate-term MOEs are less than 5 for residues greater than or equal to the limit of detection (LOD). Dislodgeable foliar residue (DFR) values for tree crops reach the LOD ($0.004 \mu\text{g}/\text{cm}^2$) 12 days after treatment. Extrapolating, DFR values for tree crops reach $\frac{1}{2}$ the LOD ($0.002 \mu\text{g}/\text{cm}^2$) for tree crops 15 days after treatment, and the MOE is 6.

For grapes, based on the maximum application rate (1 lb ai/A), short- and intermediate-term MOEs are less than 31, and 3 respectively, for residues greater than or equal to the LOD. DFR values for grapes reach the LOD ($0.004 \mu\text{g}/\text{cm}^2$) 8 days after treatment. Extrapolating, DFR values for grapes reach $\frac{1}{2}$ the LOD ($0.002 \mu\text{g}/\text{cm}^2$) for grapes 11 days after treatment, and the intermediate-term MOE is 6.

For cabbage, based on the typical mid-range application rate (2 lbs ai/A), MOEs for intermediate-term exposures are less than 25 for residues greater than or equal to the LOD. DFR values for cabbage reach the LOD ($0.002 \mu\text{g}/\text{cm}^2$) 13 days after treatment. Extrapolating, DFR values for cabbage reach $\frac{1}{2}$ the LOD ($0.001 \mu\text{g}/\text{cm}^2$) 16 days after treatment, and the MOE is 62.

Essentially, for all postapplication dermal exposure scenarios associated with tree crops and grapes, DFR levels must be extrapolated below $\frac{1}{2}$ of the LOD before MOEs greater than or equal to 100 can be achieved. For low-growing crops at an application rate of 2 lbs. ai/acre, a MOE of 71 is achieved for short-term dermal exposures, 7 days after treatment, and a MOE of 140 is

achieved for intermediate-term dermal exposures 19 days after treatment. However, a REI of 3 days can be achieved for low exposure crops after treatment at the minimum application rate of 0.25 lb ai/A with a MOE of 170.

The reentry interval (REI) on current diazinon labels (e.g., EPA Reg. No. 100-460) is 24 hours for fruit and nut crops, vegetable crops, and field crops, and 12 hours for ornamentals. California has a REI of 5 days for some crops. The significant difference between the current REI on the diazinon labels (24 hours) and that listed for California (5 days for some crops) and the REIs listed in this document is attributed to HED's use of plasma ChE as the toxicological endpoint (i.e., 0.25 mg/kg/day for short-term exposures, and 0.02 mg/kg/day for intermediate-term exposures, and an uncertainty factor of 100).

Based on chemical-specific data and information provided by the registrant for a 0.58 lb ai/acre rate of application, it is estimated that all dermal and inhalation exposures to workers re-entering greenhouses after treatment with diazinon products exceed HED's level of concern until 8-10 days after application.

Uncertainties in the postapplication exposure analyses include: the use of 100 percent dermal absorption; the use of a linear extrapolation applied to the DFR values from the study application rate (1 lb ai/A) to the maximum labeled rate (3 lbs ai/A) for tree crops; and the use of the citrus DFR values once adjusted for differences in application rates between citrus and grapes to estimate exposure for grapes.

Aggregate Exposure/Risk:

When MOEs for multiple exposure pathways differ, but exposures across those pathways must be combined under an aggregate risk assessment, HED uses the Aggregate Risk Index method (ARI method). ARIs greater than 1.0, do not exceed HED's level of concern. Results of the specific aggregate risk assessments included in this document are provided below.

Acute Aggregate Risk Estimates:

The aggregate risk assessment for acute exposures to diazinon includes one day exposures through food and drinking water, only. Exposure to diazinon from food sources (based on refined exposure estimates) and drinking water (based on surface water monitoring data, and ground water monitoring data and model estimates) do not exceed HED's level of concern for acute dietary risk for any subgroup analyzed. However, if surface water *model* estimates are used in the assessment, risk estimates for infants and children exceed HED's level of concern. HED has indicated that further refinements to residues used for sheep commodities (sheep fat and lean meat) in the acute dietary analysis may further reduce risk estimates. Given the uncertainty in the model and monitoring estimates relative to each other (10x) for surface water concentrations of diazinon, and therefore, the uncertainty relative to diazinon concentrations in actual drinking water, HED recommends that the acute exposures to diazinon in drinking water, and subsequently acute

aggregate exposure, be reassessed once surface-water sourced drinking water monitoring data on diazinon and its regulated metabolites become available for use.

Short-term Aggregate Risk:

HED has concerns for aggregate short-term exposures to diazinon for residential handlers of turf products. Risk estimates for aggregate short-term postapplication exposures to diazinon from granular formulations used to treat lawns do not exceed HED's level of concern. HED has concerns for aggregate short-term postapplication exposures to diazinon for adults and children in the home after indoor crack and crevice treatments.

Short-term aggregate risk assessments combine short-term residential exposures with average, dietary (food and drinking water) exposures. The calculated MOEs for short-term dermal exposures for residential handlers from lawn treatments are less than 85. Inhalation exposures from lawn treatments for residential handlers vary depending on application rates and exposure scenario. However, because all MOEs for dermal exposures of residential handlers are below 100, HED has not aggregated short-term exposures from food, drinking water and residential exposures for handlers. Aggregating additional exposures from food and drinking water with these residential exposures would only result in a risk estimate that would further exceed HED's level of concern. Until residential short-term dermal exposures can be mitigated for residential handlers, aggregate short-term risk estimates exceed HED's levels of concern.

Based on data from chemical-specific studies, worst-case postapplication dermal and inhalation exposures from indoor crack and crevice treatments result in MOEs less than 100 and 300, respectively. Therefore, HED has not aggregated short-term exposures from food, drinking water with postapplication residential exposures from indoor crack and crevice treatments. Aggregating additional exposures from food and drinking water with these residential exposures would only result in a risk estimate that would further exceed HED's level of concern. Until postapplication residential short-term exposures can be mitigated from indoor treatments, aggregate short-term risk estimates for postapplication exposures to diazinon exceed HED's levels of concern.

Based on data from chemical-specific studies, worst-case postapplication dermal and inhalation exposures from lawn treatments with liquid formulations of diazinon result in MOEs less than 100 and 300, respectively, and exceed HED's level of concern. Therefore, HED has not aggregated short-term exposures from food, drinking water with postapplication residential exposures from lawn treatments with liquid formulations of diazinon. Aggregating additional exposures from food and drinking water with these residential exposures would only result in a risk estimate that would further exceed HED's level of concern. Until postapplication residential short-term exposures can be mitigated from lawn treatments with liquid formulations of diazinon, aggregate short-term risk estimates for postapplication exposures to diazinon exceed HED's levels of concern.

HED has conducted short-term aggregate risk assessments, combining exposures from food, drinking water, and worst-case postapplication residential exposures from lawn treatments with

granular formulations of diazinon. Short-term aggregate risk estimates for adults combine exposures from food, drinking water, and short-term dermal and inhalation postapplication exposures from granular formulations of diazinon used on lawns. Risk estimates for these short-term aggregate exposures do not exceed HED's level of concern for adults. Short-term aggregate risk estimates for children combine exposures from food, drinking water, and short-term dermal, non-dietary oral (hand-to-mouth), and inhalation postapplication exposures from granular formulations of diazinon used on lawns. Risk estimates for these short-term aggregate exposures do not exceed HED's level of concern for children.

Chronic Aggregate Risk:

The chronic aggregate risk assessment for exposures to diazinon includes long-term, average exposures to diazinon through food and drinking. There are no residential uses that result in chronic exposure. Therefore, chronic aggregate risk estimates based on estimated exposures from food and groundwater are the same as those presented under the section on chronic drinking water risk estimates. HED concludes chronic aggregate exposures to diazinon in food and ground-water sourced drinking water do not exceed levels of concern.

Chronic aggregate risk estimates based on estimated exposures from food (based on refined exposure estimates) and surface water (based on ambient monitoring data) do not exceed HED's level of concern for chronic aggregate exposures to diazinon in food and surface-water sourced drinking water. However, *model* estimates for concentrations of diazinon in surface water (which are approximately one order of magnitude greater than the concentration estimates from monitoring data) indicate there is a potential concern for infants, children (1 to 6), and females 13+. However, given the uncertainty in the model and monitoring estimates relative to each other (10x) for surface water concentrations of diazinon, and therefore, the uncertainty relative to long-term concentrations of diazinon in actual drinking water, HED recommends that the chronic exposures to diazinon in drinking water, and subsequently chronic aggregate exposure, be reassessed once surface-water sourced drinking water monitoring data on diazinon become available for use.

Uncertainty:

In conclusion, HED notes that the following issues introduce uncertainty into the risk estimates. For acute and chronic dietary exposures, unrefined residue values in sheep fat and meat are the major contributors to the risk estimates. Better estimates of the percentage of sheep treated with diazinon (domestic and imported) will refine the exposure and risk estimates for both acute and chronic dietary assessments. Percent of crop-treated information for imported commodities may refine exposure and risk estimates. For drinking water exposures, monitoring data on diazinon and its oxon in surface-water sourced drinking water, once reviewed, may clarify discrepancies between model estimates and monitoring data for diazinon in surface water and refine drinking water risk estimates. Estimates of long-term, average concentrations of diazinon in groundwater from monitoring data would allow refinement of chronic drinking water risk estimates. Pertinent information on toxicologically significant metabolites in drinking water would also reduce uncertainty in the risk estimates. For occupational and residential exposures, dermal absorption

data would refine risk estimates, and information on toxicologically significant metabolites would reduce uncertainty in the risk estimates.

Data Requirements:

The following data are required at this time.

Product Chemistry - All pertinent generic data requirements are satisfied for the Novartis and Makhteshim "unstabilized" TGAIs, except that data pertaining to stability (OPPTS 830.6313) are outstanding for the Makhteshim TGAi and data concerning UV/visible absorption for the PAI (OPPTS 830.7050) are required for both TGAIs. All pertinent product-specific data requirements are satisfied for the Novartis 87% FI. Additional product-specific product chemistry data are required for the Prentiss 80%, 50%, 48.7%, 25%, and 10% FIs; the AgrEvo 10% and 5% FIs; and the Makhteshim 92% and 87% FIs. No product chemistry data have been submitted in support of reregistration of the Sureco 70.31%, 25%, and 12.5% FIs and the AgrEvo 25% FI. Data requirements for the repackaged Gowan and Drexel 87% FIs will be satisfied by data for the source products. The product chemistry data requirements for diazinon products are presented in the attached summary tables in the Residue Chemistry Chapter for diazinon. Refer to these tables for a listing of the outstanding product chemistry data requirements.

Residue Chemistry - Additional residue data are required for beans (lima), blueberries, celery, cucumbers, hops, dried peas, spinach, sugar beets, and Swiss chard. Additional residue data on sugar beets reflecting current label rates and PHI are necessary to determine if feed additive tolerances are necessary. The registrant has agreed to conduct limited rotational crop studies.

Occupational Exposure - The following mixer/loader/applicator data requirements were identified to support reregistration of diazinon:

- 1) Guideline 231 - Estimation of Dermal Exposure at Outdoor Sites (studies are required for handlers in double-layer body protection and chemical-resistant gloves and additional studies are required for handlers using engineering controls.
 - mixing/loading with granular formulations and emulsifiable concentrates.
 - broadcast and banding application of granular formulations.
 - application of liquids with various types of equipment (e.g. aerial, airblast, rights-of-way-sprayer, etc.).
- 2) Guideline 232 - Estimation of Inhalation Exposure at Outdoor Sites (studies are required for handlers wearing respirators and additional studies are required for handlers using engineering controls.)
 - mixing/loading with granular formulations and emulsifiable concentrates.
 - broadcast and banding application of granular formulations.
 - application of liquids with various types of equipment (e.g. aerial, airblast, rights-of-way-sprayer, etc.).

Based on the use information and data available, the following postapplication exposure data are required to support the reregistration of diazinon:

- 1) 132-1(a) foliar dislodgeable residue dissipation (for greenhouse ornamentals),
- 2) 132-1(b) soil residue dissipation,
- 3) 133-3 dermal exposure, and
- 4) 133-4 inhalation exposure: for the uses that may involve greenhouse indoor activities, and human contact with treated soil which include: pre-planting on strawberries, cabbage, turnips, tomatoes, sweet potatoes, radishes, lettuce, cucumbers, etc., and repeated foliar applications within a greenhouses to, ornamental non-flowering plants, ornamental herbaceous plants, ornamental woody shrubs and vines, and all nursery stock. Data are required using both the liquid and granule formulations.
- 5) There are no chemical specific exposure data for handling diazinon treated soil, seed/seedling treatments and sheep treatments; therefore the Agency is requiring data and/or further clarification of the use patterns involving workers handling or working with or in the treated soil, seed/seedling treatments and sheep treatments which may result in post-application exposure. These soil treatment uses are on strawberries, cabbage, turnips, tomatoes, sweet potatoes, radishes, lettuce, cucumbers, etc.

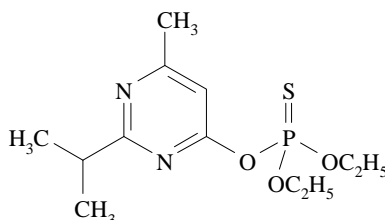
II. USE PROFILE

Diazinon [O,O-diethyl-O-(2-isopropyl-6-methyl-4-pyrimidinyl)phosphorothioate] is a nonsystemic organophosphate insecticide/acaracide registered for use on a variety of terrestrial foods and an aquatic food (watercress), livestock feeds, and livestock (sheep sprays and cattle ear tags). Since August 1986, label prohibitions against the use of diazinon on food crops grown in greenhouses have been required. It has registered non-food uses, as well, including: food/feed handling establishments, livestock areas, and indoor/outdoor residential sites. Diazinon has veterinary uses for fleas and ticks. Currently approved veterinary uses are for impregnating pet collars with diazinon. Information available for diazinon production in 1999 show 13.5 million pounds of active ingredient produced for sale. It is also an ingredient in pest strips. It is available in dust, granules, seed dressings, wettable powders, and emulsifiable solution formulations. It can be applied foliarly or as a soil treatment using ground or aerial equipment followed by incorporation for most uses. Based on available usage information, for 1987 through 1997, total annual domestic usage of diazinon is approximately 6 million pounds active ingredient. Most of this is allocated to outdoor residential uses, lawn care operators, and pest control operators. States with significant usage include California, Texas, and Florida.

III. PHYSICAL AND CHEMICAL PROPERTIES ASSESSMENT

A. Description of Chemical

Diazinon [O,O-diethyl-O-(2-isopropyl-6-methyl-4-pyrimidinyl)phosphorothioate] is a nonsystemic insecticide/nematicide.



Empirical Formula: C₁₂H₂₁N₂O₃PS
Molecular Weight: 304.3
CAS Registry No.: 333-41-5
Shaughnessy No.: 057801

B. Identification Of Active Ingredient

Pure diazinon is a colorless oil which is formulated into "stabilized" technical diazinon. Technical diazinon (≥90% pure) is an amber to brown liquid with a boiling point of 83-84 C. Technical diazinon is practically insoluble in water (40 ppm at 20 C) but is completely miscible in acetone, benzene, dichloromethane, ethanol, 1-octanol, toluene, and xylene, and is soluble in petroleum oils.

C. Manufacturing Use Products

A search of the Reference Files System (REFS) conducted 9/15/99 identified 21 diazinon manufacturing-use products (MPs) registered under Shaughnessy No. 057801. The registered diazinon MPs are listed in Table 1 and are the only products subject to a reregistration eligibility decision. We note that several products are manufactured from an unregistered "unstabilized" TGAI; data are required for the TGAI for the reregistration of diazinon.

Table 1. Registered Diazinon Manufacturing-Use Products.

Formulation	EPA Reg. No.	Registrant
87% FI	100-524	Novartis Crop Protection, Incorporated (formerly Ciba-Geigy Corp.)
56% FI	100-783	
22.4% FI	100-771	

Formulation	EPA Reg. No.	Registrant
5% FI	100-714	Prentiss, Incorporated
80% FI	655-473	
50% FI	655-463	
48.7% FI	655-500	
25% MAI FI ¹	655-595	
10% MAI FI ¹	655-401	
70.31% MAI FI ^{2,3}	769-695	Sureco, Incorporated
25% FI ⁴	769-693	
12.5% MAI FI ^{2,5}	769-691	
25% MAI FI ¹	4816-685	AgrEvo Environmental Health (formerly Fairfield American Corp.)
10% MAI FI ¹	4816-640	
5% MAI FI ¹	4816-245	
5% MAI FI ¹	4816-621	
87% FI ^{6,7}	10163-212	Gowan Company
92% FI ⁶	11678-6	Makhteshim Chemical Works Limited
87% FI ⁶	11678-20	
87% FI ^{6,7}	19713-104	Drexel Chemical Company

¹ Formulated with piperonyl butoxide and pyrethrins.

² Formulated with aliphatic or aromatic solvents.

³ Transferred from Southern Mill Creek Products Company (EPA Reg. No. 6720-201; 12/18/92).

⁴ Transferred from Southern Mill Creek Products Company (EPA Reg. No. 6720-199; 12/18/92).

⁵ Transferred from Southern Mill Creek Products Company (EPA Reg. No. 6720-197; 12/18/92).

⁶ REFS currently identifies this product as a technical; however, it is correctly identified as an FI.

⁷ Repackaged from EPA-registered products.

D. Regulatory Background

Diazinon was the subject of a Reregistration Standard dated 7/15/86 which stated that generic and product-specific product chemistry data for all MPs must be resubmitted in support of the reregistration of diazinon. An Addendum #1 to the Product Chemistry Chapter was issued 8/22/86 which required preliminary analysis of all Ts and FIs for tetraethylpyrophosphate (TEPP) or sulfur derivatives of TEPP, upper certified limits for TEPP and sulfur derivatives of TEPP, and quantitative enforcement analytical methods with supporting validation data for products in which these impurities were identified. The Diazinon Reregistration Standard-Update #1 dated 3/24/88 reiterated the requirements specified in the Reregistration Standard and noted that because the

"unstabilized" TGAI was stabilized for registration, the registered MPs would be classified as FIs. A Guidance Document was issued 12/88. Data submitted in response to the Update #1 and the Guidance Document were reviewed and summarized in the Diazinon Reregistration Standard Update dated 1/24/92. We note that the Novartis 56% and 22.4% FIs and the Gowan 87% FI were registered subsequent to issuance of the Update (3/18/96, 9/14/95, and 9/29/94, respectively).

The current status of the product chemistry data requirements for the diazinon products is presented in tables in the Residue Chemistry Chapter (Attachment IV). Refer to these tables for a listing of the outstanding product chemistry data requirements.

E. Product Chemistry Requirements

All pertinent generic data requirements are satisfied for the Novartis and Makhteshim "unstabilized" TGAIs, except that data pertaining to stability (OPPTS 830.6313) are outstanding for the Makhteshim TGAI and data concerning UV/visible absorption for the PAI (OPPTS 830.7050) are required for both TGAIs. All pertinent product-specific data requirements are satisfied for the Novartis 87% FI. Additional product-specific product chemistry data are required for the Prentiss 80%, 50%, 48.7%, 25%, and 10% FIs; the AgrEvo 10% and 5% FIs; and the Makhteshim 92% and 87% FIs. No product chemistry data have been submitted in support of reregistration of the Sureco 70.31%, 25%, and 12.5% FIs and the AgrEvo 25% FI. Data requirements for the repackaged Gowan and Drexel 87% FIs will be satisfied by data for the source products.

Provided that the registrants submit the data required in the attached data summary tables for the unregistered "unstabilized" TGAIs and the registered MPs and either certify that the suppliers of beginning materials and the manufacturing processes for the diazinon TGAIs and MPs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, HED has no objections to the reregistration of diazinon with respect to product chemistry data requirements.

IV. HUMAN HEALTH RISK ASSESSMENT

A. Hazard Assessment

The toxicology data base for diazinon is sufficient to support the Reregistration Eligibility Decision (RED).

1. Acute Toxicity

Table 2 below summarizes the results endpoints, and toxicity categories for the acute toxicity

studies.

Table 2. Summary of acute toxicity of technical Diazinon.		
Study	Results	Toxicity Category
81-1. Acute Oral-rats. MRID No.: 41407218.	LD ₅₀ = 1340 (1140-1610)mg/kg ♂ = 1160 (999-1350) mg/kg ♀ = 1250 (1080-1415) mg/kg combined sexes (95% confidence limits)	III
81-2. Acute Dermal -rabbits. MRID No.: 41407219.	LD ₅₀ > 2020 mg/kg ♀/♀	III
81-3. Acute Inhalation - rats. MRID No.: 41407220.	LC ₅₀ = > 2.33 mg/L (four hour exposure with a MMAD of 2.046 μm.).	III
81-4. Primary Ocular Irritation - rabbits. MRID No.: 41407221.	Minimally irritating.	III
81-5. Primary Dermal Irritation - rabbits. MRID No.: 41407222.	maximum irritation score 2.8 (slight irritant)	III
81-6. Dermal Sensitization - guinea pigs. MRID No.: 41407223 and 00232008	Not a sensitizer in guinea pig (Buehler assay). [Human study indicates 5-6/56 showed positive sensitization].	--
81-7. Delayed type neurotoxicity-hens. MRID No.: 44132701	No evidence of delayed type neurotoxicity at 100 mg/kg, a dose > than the LD ₅₀ ; protected by atropine and physostigmine.	--

2. Subchronic Toxicity

i. 21- Day Dermal Toxicity in Rabbits (82-2). The LOAEL is < 1 mg/kg/day based on plasma cholinesterase inhibition. The NOAEL for plasma cholinesterase inhibition was not established. New Zealand White rabbits were dosed (MRID 40660807), 4 groups of 5/sex as control, 1, 5 or 100/50 mg/kg/day of diazinon for five days/week for three weeks. Plasma cholinesterase was inhibited ($p < 0.05$ or less) at termination at all dose levels in females with there being 32%, 35% and 62% inhibition at 1, 5 and 50 mg/kg/day, but only at the 50 mg/kg/day dose in males. Red blood cell cholinesterase was statistically inhibited at 50 mg/kg/day in males (39%, based on one male) and females (32%). At 5 mg/kg brain cholinesterase was inhibited 18% in females, but not in males. At 50 mg/kg, brain cholinesterase was inhibited 28% in males (one animal) and 43% in females. The initial dose of 100 mg/kg/day was lethal (4/5 males) and reduced to 50 mg/kg/day after 7 days. No systemic effects were noted in the high dose group when the dose was reduced to 50 mg/kg/day. The rabbits were assessed for clinical signs and at day 21 were sacrificed and

necropsied and subjected to hematology and clinical chemistry including plasma, red blood cell, and brain acetyl cholinesterase inhibition assessments.

Although this 21-day dermal toxicity study on rabbits was available for use, the results indicated that rabbits, both males and females, are less sensitive to the dermal toxicity of diazinon than rats or dogs. The lesser sensitivity observed via the dermal route in rabbits is supported by the fact that the rabbit has a number of unique physiological and biochemical characteristics which can lead to a potential underestimation of the dermal toxicity of a chemical. This is particularly true of organophosphates which require biological activation to the oxon. In humans, activation of organophosphates takes place in the liver upon the exchange of oxygen for the sulfur atom. This process, however, does not occur to the same extent in the rabbit because of the high levels of arylesterase present in the rabbit blood stream. Arylesterase can rapidly detoxify organophosphates before they can reach the liver and be activated. As a result, basing the dermal toxicity study of an organophosphate solely on rabbit dermal toxicity studies may underestimate the toxicity. The dermal toxicity study in rabbits was deemed unsuitable for use in dermal risk assessments, because of unique physiological and biochemical characteristics of rabbits. Results from rabbits have the potential to underestimate the toxic effects of diazinon via the dermal route.

ii. Subchronic Oral Toxicity in Dogs (82-7). Endpoints from the 4-week and 90-day subchronic feeding studies in dogs described below were used to support the chronic dietary risk assessment, and the intermediate- and long-term dermal risk assessments.

The LOAEL was < 0.023 mg/kg/day based on plasma cholinesterase inhibition, and the NOAEL was not determined from a four week subchronic pilot study. The study (MRID 40815004) was conducted using five groups of 4/sex beagle dogs dosed with diets containing 0, 0.5, 2, 20 or 500 ppm diazinon (MG-8). These dose levels corresponded to 0.02/0.023, 0.073/0.082, 0.80/0.75 or 14.68/15.99 mg/kg/day for males/females. Plasma cholinesterase was inhibited at 0.5 ppm in females at approximately 29%, ($p < 0.01$) and in males at approximately 8% (not significant). Only at 500 ppm was red blood cell (26-39% in both males and females) and brain (44% in males, 50% in females) acetyl cholinesterase inhibited (all $p < 0.01$). Systemic toxicity was evident at 500 ppm only and included emesis and decreased body weight and feed consumption. The LOAEL for systemic toxicity is 14.68 mg/kg/day based on body weight effects. The NOAEL is 0.80 mg/kg/day.

The LOAEL was 0.020 mg/kg/day based on plasma cholinesterase inhibition in males, and the NOAEL was 0.0037 mg/kg/day from a 90-day study in dogs. The study (MRID 40815004) used 5 groups of 4/sex beagles dosed with diazinon (MG-8) at dose levels of 0, 0.1, 0.5, 150 or 300 ppm for 13 weeks. These doses correspond to 0.0034/0.0037, 0.020/0.021, 5.9/5.6 or 10.9/11.6 mg/kg/day for males/females. Plasma cholinesterase was inhibited in females at 0.5 ppm at approximately 16% (not significant) and in males at approximately 30% ($p < 0.05$). At 150 ppm, plasma cholinesterase was inhibited about 80% in both males and females. At 150 ppm, red blood cell (~25% in males and ~31% in females, $p < 0.01$) and brain acetyl cholinesterase (31% in males and 30% in females) were inhibited. At 300 ppm, brain AChE was inhibited ~42% in males and

~45% in females. The systemic LOAEL is 5.6 mg/kg/day based on decreased body weight. The NOAEL is 0.021 mg/kg/day. Systemic effects were noted at 150 ppm and included decreased body weight gain in females (34%, not significant), total protein (~1.4%) and calcium (~5%). At 300 ppm, both male and female body weight gain was decreased (33% males and 45% females), and decreased food consumption and total protein and calcium decreases were increased.

iii. Subchronic Inhalation in Rats (82-4). Endpoints from this study were selected for inhalation risk assessments. The LOAEL is $< 0.1 \mu\text{g/L}$ (converts to 0.026 mg/kg/day) and is based on plasma cholinesterase inhibition in male and female rats, and red blood cell cholinesterase inhibition in males. The NOAEL was $< 0.1 \mu\text{g/L}$ for plasma ChE and RBC AChE in males, but was $> 0.1 \mu\text{g/L}$ for RBC AChE in females and brain AChE in both sexes. A definitive NOAEL for cholinesterase inhibition was not determined. Sprague-Dawley strain rats (four groups of 15/sex) were dosed as control, 0.1, 1, 10 and 100 $\mu\text{g/L}$ of diazinon MG-8 (87% purity) for six hours/day 7 days/week in a 21-day inhalation study (MRID 40815002). No systemic effects (symptoms) were reported in response to treatment. The LOAEL and NOAEL for systemic effects were both $> 100 \mu\text{g/L}$.

At 0.1 $\mu\text{g/L}$, plasma cholinesterase was inhibited in males (30%, $p < 0.05$) and females (56%, $p < 0.05$). Progressively higher levels of inhibition were noted at higher doses. Red blood cell cholinesterase was inhibited in males (18%, $p < 0.05$) at 0.1 $\mu\text{g/L}$ and inhibition was progressively greater at higher doses. In females red blood cell cholinesterase was statistically inhibited (45%) at 1 $\mu\text{g/L}$. At 1 $\mu\text{g/L}$ brain acetyl cholinesterase was inhibited in both males (13%, $p < 0.05$) and females (15%, $p < 0.05$).

3. Chronic Toxicity and Carcinogenicity

i. Oral Toxicity Study in Rats - One Year (83-1(a)). The LOAEL and NOAEL based on inhibition of plasma cholinesterase inhibition was 0.06 mg/kg/day and 0.005 mg/kg/day, respectively. Sprague-Dawley strain rats (6 groups of 30/sex) were dosed with 0.0 (two groups), 0.1, 1.5, 125 or 250 ppm diazinon MG-8 (87.7% purity) for 98 weeks (MRID 41942002). These dose levels correspond to 0.004/0.005, 0.06/0.07, 5/6 or 10/12 mg/kg/day for males/females. The control groups (both sets) and the 250 ppm dose group had satellite groups of 10/sex that were reserved for a 4 week recovery period following dosing for 52 weeks. No systemic toxicity was evident.

Plasma cholinesterase was inhibited at 1.5 ppm in females (58%, $p < 0.01$) and in males (51%, $p < 0.05$ at termination only). It was noted that at 0.1 ppm at some assay intervals, females were inhibited up to 26% and males up to 36% but statistical significance was not attained. At 125 ppm, red blood cell cholinesterase was inhibited in males (28%, $p < 0.01$) and in females (26%, $p < 0.01$). Brain acetyl cholinesterase was inhibited at 125 ppm for males (24%, $p < 0.01$) and females (29%, $p < 0.01$). The systemic LOAEL and NOAEL were $> 12 \text{ mg/kg/day}$ and $\geq 12 \text{ mg/kg/day}$, respectively.

ii. Oral Toxicity Study in Dogs - One Year (83-1(b)). Endpoints and data from this study were used in support of the chronic dietary risk assessment. The LOAEL was 0.5 ppm (0.02 mg/kg/day) based on plasma cholinesterase inhibition in females. The NOAEL was 0.1 ppm (0.0037 mg/kg/day). Five groups of 4/sex beagle dogs were dosed with 0, 0.1, 0.5, 150 or 300/225 ppm diazinon (MG-8) for 52 weeks (MRID 41942001). The high dose group was initiated at 300 ppm but was reduced after 14 weeks to 225 ppm. These dose levels corresponded to 0.0032/0.0037, 0.015/0.020, 4.7/4.5 or 7.7/9.1 mg/kg/day. At 0.5 ppm, plasma cholinesterase was inhibited in females 18-40% ($p < 0.01$). At 150 ppm, red blood cell cholinesterase was inhibited in males (25-34%, $p < 0.01$) and in females (26-33%, $p < 0.01$). Plasma cholinesterase was inhibited at 0.1 ppm (9-28%, $p < 0.05$) in females and at 0.5 ppm 5-25% ($p < 0.05$) in males. Brain acetyl cholinesterase was inhibited at 150 ppm in females (26%, $p < 0.05$) and males (15%, not significant). At 225/300 ppm, male brain inhibition reached 25% but was not significant while female brain inhibition reached 35% ($p < 0.05$).

Systemic toxicity was evident at 150 ppm based on decreased body weight gain (up to 64%) and food consumption (up to 27%) particularly in males and increased serum amylase (24-59%). The LOAEL for systemic toxicity was 4.5 mg/kg/day based on body weight gain decrease. The NOAEL was 0.02 mg/kg/day.

iii. Oral Toxicity in Rats - Two Years (83-2(a)). At the doses tested, there was no evidence of carcinogenicity related to treatment with diazinon. The LOAEL for systemic effects was > 40 mg/kg/day. In a carcinogenicity toxicity study (MRID 00073372), diazinon (98% purity) was administered to groups of Fischer 344 (50/sex) rats at either 400 or 800 ppm (estimated to be 20 and 40 mg/kg/day) for 103 weeks. The control group consisted of 25/sex untreated rats. No systemic effects were reported. The study itself did not provide a basis for concluding that adequate doses were assessed. The dose levels tested are well established from other studies to be moderately strong inhibitors of plasma, red blood cell, and brain cholinesterase. No evidence of compound related tumors was apparent in this study.

iv. Oral Toxicity in Mice - Two Years (83-2(b)). At the doses tested, there was no evidence of carcinogenicity related to treatment with diazinon. The LOAEL for systemic effects was > 29 mg/kg/day. In a carcinogenicity toxicity study (MRID 00073372) diazinon (98% purity) was administered to 50/sex B63CF1 strain mice in their diets at dose levels of 100 or 200 ppm (estimated to be 14 and 29 mg/kg/day for 103 weeks. The control group consisted of 25/sex untreated mice. No systemic toxicity.

4. Developmental Toxicity

i. Oral Teratology Study in Rats (83-3(a)). No developmental toxicity was seen at the highest dose tested. For maternal toxicity, the LOAEL was 100 mg/kg/day based on body weight gain decrease and the NOAEL was 20 mg/kg/day. The NOAEL for developmental toxicity was 100 mg/kg/day. Four groups of 27 assumed pregnant rats (Charles River CrI. COBSTM CDTM (SD)(BR)) were dosed as control, 10, 20 or 100 mg/kg/day on days 6 through 15 of gestation.

Diazinon (purity not specified) was suspended in 0.2% carboxymethyl cellulose and the rats were dosed by gavage at a rate of 10 mL/kg/day. The rats were sacrificed on day 20 of gestation. MRID No.: 00153017. At 100 mg/kg/day maternal body weight gain was decreased particularly during the 6-10 day interval (-11±2 grams vs +14±2 grams for the control). After that interval the rats showed recovery but net gain was 25% less for the high dose group at sacrifice. The mean fetal weight in the 100 mg/kg/day dose group was increased (~6%) and the mean number of live fetuses in this groups was slightly reduced. There were also noted slight increases in pre and postimplantation loss. An increase in rudimentary T-14 ribs that was within historical control range was also noted.

ii. Oral Teratology Study in Rabbits (83-3(b)). No developmental toxicity was seen at the highest dose tested. No compound related effects on the fetuses were evident. The LOAEL for maternal toxicity is 100 mg/kg/day based on deaths. The NOAEL for maternal toxicity is 25 mg/kg/day. The NOAEL for developmental toxicity is 100 mg/kg/day. In a developmental toxicity study (MRID 00079017) diazinon (89.2% purity suspended in 0.2% carboxymethyl cellulose) was administered by gavage (1 mL/kg) to four groups of assumed pregnant New Zealand White Rabbits at dose levels of 0 (vehicle control), 7, 25 or 100 mg/kg/day on days 6 to 18 of gestation. At 100 mg/kg/day there were 9 deaths in the group of 22 does (40.9%). Clinical symptoms including tremors and convulsions and body weight gain decreases as well as gastrointestinal hemorrhages and erosions were noted.

5. Reproductive Toxicity

i. 2-Generation Reproductive Toxicity Study in Rats (83-4). The LOAEL was 100 ppm (6.69 mg/kg/day) based on decreased parental weight gain, and the NOAEL was 10 ppm (0.67 mg/kg/day). The LOAEL was 100 ppm (6.69 mg/kg/day) based on pup mortality and decreased weight gain. The NOAEL was 10 ppm (0.67 mg/kg/day). In a multi generation reproduction study (MRID 41158101), four groups of 30/sex Sprague-Dawley strain rats were dosed as control, 10, 100 or 500 ppm of diazinon (equivalent to 0, 0.67, 6.69 or 35.15 mg/kg/day in male, and 0, 0.77, 7.63 or 41.43 mg/kg/day in females) for 10 weeks and mated (1:1) to produce F1 litter pups. The F1 litters were culled and mated to produce the an F2 generation. In the parental groups, at 100 ppm there was decreased weight gain (5-6% persistent for males in the second parental group and transitory for females.). At 500 ppm there were tremors in females; decreased male and female mating and fertility indices (second parental group) and increased gestation length. Dystocia and death were slightly increased but not definitely associated with treatment. In the pups, at 100 ppm there was mortality and decreased weight gain during lactation. At 500 ppm there were decreases litter size and viable pups.

6. Mutagenicity (84-2).

Study Identification	Results/Comments
Gene Mutation	

Study Identification	Results/Comments
<p>1. <u>Salmonella typhimurium/ Escherichia coli.</u> MRID No.: 41557404 HED Document No.: 010062</p> <p>2. <u>Mouse lymphoma L5178Y TK[±] for- ward gene mutation assay.</u> MRID Nos.: 40660802 and 41119701 HED Document Nos.: 007059 and 007553</p>	<p>Independently performed tests were negative in <u>S.typhimurium</u> strains TA1535, TA1537, TA98 and TA 100 and <u>E.Coli</u> strains WP2 <u>uvrA⁻</u> up to the highest dose tested (5000 $\mu\text{g}/\text{plate} \pm \text{S9}$). The test was negative up to the cytotoxic levels (120 $\mu\text{g}/\text{mL}$ -S9 and 60 $\mu\text{g}/\text{mL}$ +S9).</p>
Chromosome Aberration	
<p><u>Mouse micronucleus assay.</u> MRID No.: 40660805 and 41603201 HED Document No.: 007229 and 010062</p>	<p>Negative in male and female CD-1 mice up to lethal doses administered by gavage (60 or 120 mg/kg). No evidence of cytotoxic effect on the target cells.</p>
Other Mutagenic Mechanisms	
<p>1. <u>In vitro sister chromatid ex-change (SCE) in human lymphocytes.</u> MRID No.: 41577301 HED Document No.: 010062 and 010722</p> <p>2. <u>In vivo SCE male ICR mice</u> MRID No.: 41687701 HED Document No.: 009619</p> <p>3. <u>In vivo SCE in female CD-1 strain mice.</u> MRID No.: 43060601 HED Document No.: 010945</p> <p>4. <u>Primary rat hepatocyte un-scheduled DNA synthesis.</u> MRID No.: 41557405 HED Document No.: 010062</p>	<p>Study was weakly positive showing reproducible but not dose-related significant increases in SCE frequency over an S9-activated concentrations range of 6.68-66.8 $\mu\text{g}/\text{mL}$. Higher levels (200 $\mu\text{g}/\text{mL}$ +S9 or 66.8 $\mu\text{g}/\text{mL}$ -S9) were cytotoxic. The test was negative at oral doses of 10-100 mg/kg. Overt toxicity and bone marrow cytotoxicity were apparent in the treated males at the highest dose tested. The test was negative in female mice at oral doses of 150-175 mg/kg. Overt toxicity and bone marrow cytotoxicity were apparent in the treated females at concentrations ≥ 150 mg/kg. Independently performed tests were negative up the highest dose tested (120 $\mu\text{g}/\text{mL}$). Higher levels (≥ 163.1 $\mu\text{g}/\text{mL}$) were insoluble.</p>

7. Metabolism (85-1)

In this study (MRID 41108901) a series of experiments were run with ^{14}C labeled diazinon in Sprague-Dawley strain rats. After 24 hours most of the ^{14}C was recovered in the urine (58.2% ♀ and up to 93.3% ♂) and smaller amounts (<2.5%) in the feces. After 7 days recovery was 96.7%

to 100.25% and < 1% of the label remained in the tissues. The highest level was in the blood. Three major metabolites were identified in the urine to indicate that diazinon is metabolized to liberate the pyrimidinyl group that is oxidized and excreted. Only trace amounts of parent diazinon were present in the urine or feces. Refer to DER for chemical identification of the metabolites.

8. *Dermal Absorption (85-3)*

There is no acceptable dermal absorption/penetration study available for diazinon. The HIARC selected a 100% dermal absorption factor based on the lack of an acceptable dermal absorption study and similarity of results (mortality) observed at the same dose (100 mg/kg/day) via the oral (in the developmental toxicity study) and dermal (21-day dermal) routes in the same species (rabbits). Following oral administration in the developmental study (MRID No. 00079017), 9 of 22 dams died at 100 mg/kg/day and in the 21-day dermal study (MRID No. 40660807), 4/5 males died at 100 mg/kg/day. The LD₅₀ studies were compared because of the lack of a common toxicological endpoint in the oral and dermal studies. No cholinesterase activity was measured in the oral developmental studies in rat or rabbits and there is no dermal toxicity study in rats available in the database.

Information submitted to support a 3.85 percent dermal absorption factor in humans was found to be insufficient. The study submitted had the following citation: Wester, R.C., et al., "Percutaneous absorption of diazinon in humans", Food Chemistry and Toxicology, Volume 31, No. 8, pp. 569-572, 1993. Specifically, detailed information on the material tested, material dosed, method of application, sample collection, observations and control of the human test subjects, and analysis of data were lacking. HED recommends the appropriate information be organized, properly formatted, and resubmitted to the Agency for review before a determination as to the validity of the dermal absorption factor can be considered further

9. *Neurotoxicity*

i. Acute Neurotoxicity in Rats (81-8). Endpoints from this study were selected for use in the acute dietary risk assessment, and the short-term dermal risk assessments. In this 2 part study, the LOAEL was 250 mg/kg based on miosis and hypoactivity. The NOAEL was 100 mg/kg, but this is considered a threshold dose level. The behavioral effects and potential for inhibition of acetyl cholinesterase of diazinon (MG87%) was assessed in Sprague-Dawley Crl:CD^RBR/VAF/Plus strain rats (MRID 44219301). In Part 1 (behavioral effects), four groups of 5 rats/sex were dosed with 0, 100, 250 or 500 mg/kg of diazinon (undiluted) and additional groups of females were dosed with 25 or 50 mg/kg and the rats observed for clinical signs for 14 days. At 100 mg/kg, females were noted to have one incident of hypoactivity. At 250 and/or 500 mg/kg, miosis, hypoactivity, fur staining, and/or loss of pain reflex and at 500 mg/kg there was one death. These findings were corroborated by the cholinesterase inhibition part of the study which also demonstrated miosis at 100 mg/kg in a single male rat.

In Part 2, the LOAEL was 2.5 mg/kg based on 61% plasma cholinesterase inhibition in females,

and the NOAEL was 0.25 mg/kg. Seven groups of males were dosed as control, 0.05, 0.5, 1, 10, 100 or 500 mg/kg and seven groups of females were dosed as control, 0.05, 0.12, 0.25, 2.5, 25 or 250 mg/kg and sacrificed ~24 hours later. Observations on their behavior reactions were noted and the blood and brain were assessed for cholinesterase and acetyl cholinesterase inhibition. The precision of the assays was considered fair to poor but not sufficiently poor to preclude an assessment of the potential for diazinon to and acetyl cholinesterase inhibit. Plasma cholinesterase was inhibited at 2.5 mg/kg in females (61%) and at 10 mg/kg in males (44%). Red blood cell acetyl cholinesterase was inhibited at 25 mg/kg in females (35%) and at 100 mg/kg in males (49%). Brain acetyl cholinesterase was inhibited at 25 mg/kg in females (36%, not significant) and at 250 mg/kg (70%) and at 500 mg/kg in males (69%).

B. Dose Response Assessment

1. Special Sensitivity to Infants and Children

Prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of rats or rabbit fetuses to *in utero* exposure to diazinon. There was no indication of increased susceptibility in the fetuses as compared to parental animals in the two generation reproduction study. In the prenatal developmental studies, no developmental toxicity was seen at the highest dose tested, and in the two-generation reproduction study, effects in the offspring were observed only at treatment levels which resulted in evidence of parental toxicity. On the basis of the weight-of-the-evidence, it was determined that a developmental neurotoxicity study is not required (RfD Report date 6/17/97).

The FQPA Safety Factor Committee met on June 15 and 16, 1998 to evaluate the hazard and exposure data for diazinon and recommend application of the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996), to ensure the protection of infants and children from exposure to these pesticides.

The FQPA Safety Factor Committee has determined that the 10x FQPA safety factor can be reduced to 1x for diazinon based on the following factors (FQPA Safety Committee Report dated August 6, 1998):

- (a) In prenatal developmental toxicity studies following *in utero* exposure in rats and rabbits, there was no evidence of developmental effects being produced in fetuses at lower doses as compared to maternal animals nor was there evidence of an increase in severity of effects at or below maternally toxic doses.
- (b) In the pre- and postnatal two-generation reproduction study in rats, there was no evidence of enhanced susceptibility in offspring when compared to adults (i.e., effects noted in offspring occurred at maternally toxic doses or higher).

- (c) There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies.
- (d) There is no concern for positive neurological effects from the available neurotoxicity studies or for histopathology in the central nervous system from the other toxicological studies (e.g., subchronic rat, chronic dog, chronic mouse and rat).
- (e) The toxicology data base is complete and there are no data gaps according to the Subdivision F Guideline requirements.
- (f) Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening-level drinking water exposure assessment.

2. Toxicology Endpoint Selection

On July 27, 1998, the Agency announced that it is deeply concerned about the conduct of pesticide health effects on human subjects and consulted with the FIFRA Scientific Advisory Panel and the Scientific Advisory Board (SAP/SAB) about the application of stringent ethical standards to any studies. The SAP/SAB discussed the use of the human studies at their meeting on December 10 and 11, 1998. At this time, the Agency has not yet received the response to its consultation with the SAP/SAB and is continuing to work on its approach to the critical ethical questions.

In light of the developing Agency policy on use of toxicology studies employing human subjects, and pending reassessment of human studies for considerations of the ethical acceptability of such studies, HED has reconsidered the toxicology database for diazinon and has for the chronic dietary, as well as, occupational and residential dermal exposure risk assessments, used toxicology endpoints from animal studies. On February 16, 1999 and again on March 4, 1999, the Health Effect Division's (HED) Hazard Identification Assessment Review Committee (HIARC) reviewed the toxicology database for diazinon and selected doses and toxicology endpoints for risk assessment, based solely on animal toxicity studies as presented in Table 3.

Table 3. Summary of Toxicity Endpoints			
EXPOSURE SCENARIO	DOSE	ENDPOINT	STUDY
Acute Dietary	NOAEL=0.25 mg/kg	Plasma cholinesterase inhibition	Acute Neurotoxicity - Rat Special Study-Rat
	UF =100x FQPA = 1x	Acute PAD = 0.0025 mg/kg/day	
Chronic Dietary	0.02 mg/kg/day	Consistent pattern of no adverse effects on cholinesterase inhibition.	4 week, 90 day and 1-year studies in dog 4 week, 90 day and 2 -year studies in rat

Table 3. Summary of Toxicity Endpoints			
EXPOSURE SCENARIO	DOSE	ENDPOINT	STUDY
	UF= 100x FQPA = 1x	Chronic PAD = 0.0002 mg/kg/day	
Dermal absorption	A dermal absorption factor of 100% was selected for the following occupational and residential risk assessments. The 100% oral equivalent dermal absorption value is based on the similarity of the results (mortality) observed at the same dose (100 mg/kg/day) and in the same species (rabbits) via oral (9/22 deaths) in the developmental and dermal (4/5 deaths) in the 21-day dermal toxicity studies, and lack of an acceptable dermal absorption study.		
Short-Term (Dermal) ^a	Oral NOAEL= 0.25 mg/kg/day MOE of 100 required	Plasma cholinesterase inhibition.	Acute Neurotoxicity - Rat Special study -Rat
Intermediate-Term (Dermal) ^a	0.02 mg/kg/day MOE of 100 required	Plasma cholinesterase inhibition	90 day and 1-year Studies in dogs
Long-Term (Dermal) ^a	0.02 mg/kg/day MOE of 100 required	Consistent pattern of no adverse effects on cholinesterase inhibition.	4 week, 90 day and 1-year studies in dog 4 week, 90 day and 2 - year studies in rat
Inhalation (Any Time Period)	LOAEL=0.1 µg/L MOE of 300 required	Plasma cholinesterase inhibition	21-Day Inhalation - Rat

a = Since a dermal absorption study was not available, oral values were selected, and, 100% dermal absorption factor used for route-to-route extrapolation based on the similarity of results following oral and dermal administration of diazinon.

a. Acute Dietary (Acute Reference Dose)

An acute reference dose (0.0025 mg/kg/day) was derived from an acute neurotoxicity study in the rat. Doses based on the endpoint of cholinesterase inhibition were selected from this study for use in the acute dietary risk assessment. The LOAEL is 2.5 mg/kg/day based on 61% plasma cholinesterase inhibition in females. The NOAEL is 0.25 mg/kg/day. The uncertainty factors selected for this risk assessment were 10x for intra-species uncertainty and 10x for inter-species uncertainty for a total uncertainty factor (UF) of 100x. The additional safety factor for special sensitivity in infants and children was reduced to 1x. The resultant acute population-adjusted dose for acute dietary risk assessment is:

$$\text{Acute PAD} = 0.25 \text{ mg/kg/day (NOAEL)} \div 100 \text{ (UF)} = 0.0025 \text{ mg/kg/day}$$

As per current Office of Pesticide Programs (OPP) policy, the acute reference dose (RfD) modified by an FQPA safety factor is referred to as the Acute Population-Adjusted Dose (aPAD). Because the FQPA safety factor was reduced to 1x for diazinon, the acute PAD is equal to the acute RfD.

b. Chronic Dietary (Chronic Reference Dose)

A chronic reference dose was derived from the results *in toto* from seven oral feeding studies (in dogs from 4 week, 90-day, and 1-year feeding studies, and in rats from a 28-day feeding study, a 90-day feeding study, a 90-day neurotoxicity study, and a 2 year feeding study). Results from these studies demonstrated that the 0.02 mg/kg/day dose level was consistent with a pattern of no adverse effects. The uncertainty factors selected for this risk assessment were 10x for intra-species uncertainty and 10x for inter-species uncertainty for a total uncertainty factor (UF) of 100x. The additional safety factor for special sensitivity in infants and children was reduced to 1x. The resultant chronic population-adjusted dose for chronic dietary risk assessment is:

$$\text{Chronic PAD} = 0.02 \text{ mg/kg/day (NOAEL)} \div 100 \text{ (UF)} = 0.0002 \text{ mg/kg/day}$$

As per current Office of Pesticide Programs (OPP) policy, the chronic reference dose (RfD) modified by an FQPA safety factor is referred to as the Chronic Population-Adjusted Dose (cPAD). Because the FQPA safety factor was reduced to 1x for diazinon, the chronic PAD is equal to the chronic RfD.

In the first three studies in rats, the 0.02 mg/kg was clearly established as a NOAEL based upon statistically significant plasma cholinesterase inhibition at the next higher doses. In the two year feeding study, the dose levels did not include a 0.02mg/kg level, but the lowest two doses, 0.004/0.005 mg/kg in males and females, respectively and 0.06/0.07 in males and females, respectively, bracketed this level. Although at the 0.06 mg/kg level there was statistically significant depression in plasma cholinesterase in females in 4/5 time point measurements, the males (0.07 mg/kg) showed much more variability at this dose and had statistically significant plasma cholinesterase depression only in 1/5 time point measurements. At the lowest dose, 0.004 mg/kg, the males exhibited the same variability in plasma cholinesterase measurement although none of the levels reached statistical significance. Given the fact that there is no consistent pattern of plasma cholinesterase between the sexes, and the 0.06 mg/kg level appears to be a minimal effect level while the 0.004 mg/kg level is clearly a no-effect level, the 0.02 mg/kg level, common to the other three studies, was judged to be an overall NOAEL level for the rat.

The data for the dog which were considered included: a 4-week pilot feeding study, a 90-day feeding study and a one-year feeding study. Each of these studies had a common dose level of 0.02 mg/kg. In each of these studies the only effect seen at that dose level was plasma cholinesterase inhibition. In the 4-week pilot only females had a statistically significant inhibition of plasma cholinesterase which appeared to reach steady state between 14-25 days of dosing. In the 90-day study only males had a statistically significant inhibition of plasma cholinesterase at 0.02 mg/kg and only on days 29 and 86. In this study, steady state levels of plasma cholinesterase inhibition were reached between days 30 and 90. In the one year study, there were statistically significant decreases in plasma cholinesterase in females in 2/4 time point measurements at the lowest dose of 0.0037, but these decreases were considered not biologically relevant because of the inconsistency across time, and the variability of the magnitude of the decreases. At the next dose, 0.02 mg/kg, the only effect observed was statistically significant plasma cholinesterase inhibition in females across all time points and in males only midway in the study at day 176. No other effects were

seen in any of the studies at the 0.02 mg/kg dose. The plasma cholinesterase inhibition at 0.02mg/kg is considered to be a minimal or borderline effect in the dog since there were no effects on either the blood or brain cholinesterase levels, and there was no consistent pattern of cholinesterase inhibition between the sexes at this level.

In summary, using a weight-of-the-evidence approach, the chronic dietary endpoint is based upon the results of seven studies in the dog and rat which point to 0.02 mg/kg/day as the appropriate level on which to conduct the chronic dietary risk assessment. Although 0.02 mg/kg/day was selected based on the results of short- and long-term studies, no additional uncertainty factors were deemed necessary since: 1) the principal effect (plasma cholinesterase inhibition) was considered to be minimal or borderline, primarily there were no other effects observed at this dose (e.g., no red blood cell or brain cholinesterase inhibition nor clinical signs of toxicity or systemic effects), and there was no consistent pattern of cholinesterase inhibition between the sexes at this level; 2) a steady state of plasma cholinesterase inhibition was reached by 30 to 90 days in the dog; and 3) this dose (0.02 mg/kg/day) was a clear NOAEL in rats.

c. Carcinogenicity Classification

Based on the lack of evidence of carcinogenicity studies in mice and rats diazinon is classified as a **“not likely human carcinogen”**.

d. Dermal Absorption Factor

An acceptable dermal absorption study is not available for diazinon. However, based on the similarity of results observed following the oral and dermal administration of diazinon, mortality observed at the same dose (100 mg/kg/day) via the oral and dermal routes in the same species (rabbits), the HIARC selected a 100% default value (equivalent to oral absorption) for risk assessment. Based on the available data, a dermal absorption factor of 100% has been used for risk assessment.

e. Short-Term Dermal

The endpoint selected for use in risk assessments based on short-term dermal exposures is 0.25 mg/kg/day based on the inhibition of plasma cholinesterase. This endpoint was derived from the acute neurotoxicity study in rats and is the same endpoint selected as the basis of the acute RfD for the acute dietary risk assessment. In the absence of a dermal absorption study and the similarity of results observed following the oral and dermal administration of diazinon, a default dermal absorption factor of 100% was selected for risk assessments based on short-term dermal exposure. The uncertainty factors selected for this risk assessment were 10x for intra-species uncertainty and 10x for inter-species uncertainty for a total uncertainty factor (UF) of 100x. That is, a MOE greater than 100 would not exceed HED's level of concern.

Although a 21-day dermal toxicity study on rabbits was available for use, the results indicated that rabbits, both males and females, are less sensitive to the dermal toxicity of diazinon than rats or dogs. The lesser sensitivity observed via the dermal route in rabbits is supported by the fact that the rabbit has a number of unique physiological and biochemical characteristics which can lead to a potential underestimation of the dermal toxicity of a chemical in other species. This is particularly true of organophosphates which require biological activation to the oxon. In humans, activation of organophosphates takes place in the liver upon the exchange of oxygen for the sulfur atom. This process, however, does not occur to the same extent in the rabbit because of the high levels of

arylesterase present in the rabbit blood stream. Arylesterase can rapidly detoxify organophosphates before they can reach the liver and be activated. As a result, basing the dermal toxicity study of an organophosphate solely on rabbit dermal toxicity studies may underestimate the toxicity in other species.

f. Intermediate-Term Dermal

The endpoint selected for use in risk assessments based on intermediate-term dermal exposures is 0.02 mg/kg/day based on the inhibition of plasma cholinesterase. This endpoint was derived from the 90-day and 1 year feeding studies in dogs and is the same endpoint selected as the basis of the chronic RfD for the chronic dietary risk assessment. A default dermal absorption factor of 100% was selected for risk assessments based on intermediate- and long-term dermal exposure based on the same rationale given above. The uncertainty factors selected for this risk assessment were 10x for intra-species uncertainty and 10x for inter-species uncertainty for a total uncertainty factor (UF) of 100x. That is, a MOE greater than 100 would not exceed HED's level of concern.

In the 90-day dog feeding study, no effects were observed in either sex at the lowest dose of 0.0034 mg/kg/day in males and 0.0037 mg/kg/day in females. At the next higher dose of 0.02 mg/kg/day (both sexes), the only effect noted was plasma ChE inhibition reaching statistical significance in males only on days 29 and 86. However, the magnitude of inhibition in males was consistent across time on the days measurements were taken during the study [day 29 (29%), day 56 (27%), day 86 (30%)]. Corresponding values for females (expressed as percent of inhibition) ranged from 15 to 17% and were not statistically significant. Examination of the pattern of plasma ChE activity over time indicated that a steady state level of inhibition was reached by 90 days and possibly as early as 30 days (in other words, no considerable increase in plasma cholinesterase inhibition would be expected after 30 to 90 days of continuous dosing). This observation was supported by a similar examination of the blood cholinesterase data in the 1 year study (which also contained a measurement time point at approximately 90 days).

The rationale for not using the 21-day dermal toxicity study in rabbits is provided above under the short-term dermal endpoint selection section.

g. Long-Term Dermal

The endpoint selected for use in risk assessments based on long-term dermal exposures is 0.02 mg/kg/day based on the inhibition of plasma cholinesterase. This endpoint was derived from the 4 week, 90-day, and 1 year and 28-day feeding studies in dogs, 90-day and 90-day neurotoxicity and chronic feeding studies in rats, and is the same endpoint selected as the basis of the chronic RfD for the chronic dietary risk assessment (as described above in section b. Chronic Dietary RfD). A default dermal absorption factor of 100% was selected for risk assessments based on long-term dermal exposure using the same rationale as given above. The uncertainty factors selected for this risk assessment were 10x for intra-species uncertainty and 10x for inter-species uncertainty for a total uncertainty factor (UF) of 100x. That is, a MOE greater than 100 would not exceed HED's level of concern.

h. Inhalation (Any Time Period)

The endpoint selected for use in risk assessments based on inhalation exposures for any time period of exposure is 0.026 mg/kg/day based on the inhibition of plasma cholinesterase in both sexes and red blood cell cholinesterase inhibition in males. This endpoint is based on a LOAEL of 0.1 ug/L

that was derived from the 21-day inhalation toxicity study in rats. One hundred percent absorption (100%) is assumed for the risk assessments. The equation below shows the conversion from the endpoint (dose) in ug/L to mg/kg body weight/day.

0.026 mg/kg/day =

$$\frac{0.1 \mu\text{g/L} \times 10.26 \text{ L/hr (RV)} \times 6 \text{ hrs/day (duration)} \times 1 \mu\text{g}/1000 \text{ mg (conversion)}}{0.236 \text{ kg (body weight)}}$$

This dose should be used for risk assessments based on short-, intermediate-, and long-term inhalation exposures. The uncertainty factors selected for this risk assessment were 10x for intra-species uncertainty, a 10x for inter-species uncertainty, and since a NOAEL was not established for cholinesterase inhibition, an additional 3x factor is required for inhalation exposure risk assessments, for a total uncertainty factor (UF) of 300x. That is, a MOE greater than 300 would not exceed HED's level of concern.

i. Human Data

It is current Agency policy to make no final regulatory decision based on a human study until a new policy has been developed to ensure that such studies meet the highest scientific and ethical standards. In the absence of a policy, the Agency has selected doses and endpoints to calculate dietary and non-dietary risk based solely on animal studies.

In a special study with humans (males only), groups of 3 volunteers were dosed with 0.02 or 0.025 mg/kg/day of diazinon (a.i. from Diazinon 50WP) in corn starch by capsule for 38 or 43 days (MRID 00091536). A control group of 3 was dosed with corn starch only. The LOAEL was 0.025 mg/kg/day based on plasma cholinesterase inhibition. The NOAEL was 0.02 mg/kg/day. Frequent assessments were made every 2 to 3 days of the blood for plasma cholinesterase and red blood cell acetyl cholinesterase. All three volunteers showed inhibition ranging from 8 to 38% in the 0.025 mg/kg/day dose group. Although two of the three volunteers dosed with 0.02 mg/kg/day showed consistent depression ranging from 9 to 30% of plasma cholinesterase relative to their pretest values, a definite conclusion of significant plasma cholinesterase inhibition could not be established. Red blood cell acetyl cholinesterase was not inhibited.

On January 14, 1999, using the parameters developed for evaluation of the human studies, the HIARC evaluated the study conducted in humans subjects with diazinon (MRID 00091536). The HIARC classified this study as *unacceptable* because an audit carried out in 1980 (Clements report) classified it as "INVALID" based on the following findings: 1) no physician oversight; 2) no rationale for the 'normalization' factor used in data reporting; 3) no analysis of capsules or record of specific dose administered; and 4) no raw data available.

3. Dietary Exposure and Risk Characterization

a. Dietary Exposure - Food Sources

A search on the Agency's Reference Files System (REFS) on 09/15/99 indicates that there are twelve diazinon end-use products registered to Novartis with food/feed uses. These products are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
100-445	6/90	2% D	D.Z.N. Diazinon 2D
100-456 ^a	8/96	2 lb/gal EC	D.Z.N. Lawn and Garden Insect Control
100-460 ^b	2/97	50% WP	D.Z.N. Diazinon 50W Insecticide
100-461	3/97	4 lb/gal EC	D.Z.N. Diazinon AG500
100-463	4/96	4 lb/gal EC	D.Z.N. Diazinon 4E
100-469	7/96	14% G	D.Z.N. Diazinon 14 G
100-528 ^a	10/96	5% G	D.Z.N. 6000 Lawn and Garden Insect Control
100-926	9/98	2% D	D.Z.N. Diazinon Garden Insect Dust
100-687	11/96	0.4 lb/gal EC	D.Z.N. 5.0 EC
100-770 ^a	10/96	2 lb/gal EC	D.Z.N. Diazinon Lawn and Garden WBC
100-784	2/97	4.5 lb/gal SC/L	D.Z.N. Diazinon AG600 WBC
100-785	11/96	4.5 lb/gal SC/L	D.Z.N. Diazinon Indoor/Outdoor WBC

^a These products are registered for use in the home lawn and garden only and are therefore not summarized in Table A.

^b Includes SLN No. CA810005.

A comprehensive summary of the registered food/feed use patterns of diazinon based on the above labels has been presented in the revised Residue Chemistry Chapter dated 4/12/00 (Attachment IV). The conclusions regarding reregistration eligibility of diazinon for the crops listed in this chapter are based on the use patterns registered by the basic producer, Novartis, and summarized in the tolerance reassessment summary of this document. All end-use product labels (e.g., MAI labels, SLNs, and products subject to generic data exemption) must be amended such that they are consistent with the basic producer labels. (Guideline 860.1200).

(i). Nature of the Residue in Plants and Animals

The qualitative nature of the residue in plants is adequately understood pending review of confirmatory data from existing lettuce and green bean metabolism studies. Acceptable metabolism studies are available on sweet corn and potato. The HED Metabolism Assessment Review Committee (MARC) has determined that the residues of concern in plants and animals are diazinon, hydroxy diazinon, and diazoxon. For enforcement purposes, diazinon, per se will be included in the tolerance expression. However, the MARC recommended that residues of diazinon, and its metabolites, hydroxy diazinon and diazoxon, should be included in dietary risk assessment if they are found to be present or their concentration levels could be estimated for foods. Both of these metabolites are considered to be cholinesterase inhibitors. Residue data for plant commodities should include analyses for all three compounds.

Based on a review of adequate plant metabolism studies for apples, lettuce, corn, potatoes, and green beans, no residues of the diazinon oxon or hydroxy diazinon were identified in either organic or aqueous fractions. All of the diazinon metabolites were identified as pyrimidine compounds or glucose conjugates of these compounds. Neither of these metabolites or their conjugates contain the cholinesterase inhibiting moiety. Consequently, they are not considered to be of significant

toxicological concern for cholinesterase inhibition.

The qualitative nature of the residue in animals is adequately understood based upon acceptable poultry and ruminant metabolism studies. The HED Metabolism Committee has determined that the residues of concern in animals are diazinon, hydroxy diazinon, and diazoxon. For enforcement purposes, diazinon, per se, will be included in the tolerance expression. However, residues of diazinon, and its metabolites, hydroxy diazinon and diazoxon, should be included in dietary risk assessment if they are found to be present or their concentration levels could be estimated for foods. Both of these metabolites are considered to be cholinesterase inhibitors. Residue data for animal commodities should include analyses for all three compounds.

(ii). Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of diazinon. Ciba-Geigy Method AG-550 (along with modifications) is a GC/FPD method that adequately recovers diazinon, diazoxon, and hydroxydiazinon from plant and animal matrices, and is the registrant's proposed enforcement method. As this method is essentially a modification of the Luke multiresidue method, independent laboratory validation may not be required pending radiovalidation with samples from the metabolism studies.

The FDA PESTDATA database dated 1/94 (PAM, Vol. I, Appendix I) indicates diazinon is completely recovered using FDA Multiresidue Protocols D and E (PAM, Vol. I Sections 232.4 and 311.1/212.2). Diazoxon and hydroxy diazinon are also completely recovered using Protocol D.

(iii). Storage Stability

Storage stability data are available indicating that diazinon and hydroxydiazinon are stable in/on frozen raw agricultural commodities (RACs) for up to 26 months. Diazoxon is not stable (<3 months). The registrant intends to conduct storage stability testing on residues in processed commodities, meat, and milk. However, the registrant may wish to note that tolerances for residues of diazinon in *cattle, meat, meat byproducts, and fat* are being recommended for revocation based on a determination that category 180.6(a)3 applies to these commodities, and that the establishment of a tolerance for milk is not warranted. Also additional stability studies are also being conducted on diazoxon and hydroxydiazinon to support special studies underway to determine the dissipation of diazoxon in fresh produce.

(iv). Residues in Raw Agricultural Commodities and Processed Food/Feed

Data requirements for magnitude of the residue of diazinon in plants for most raw agricultural commodities have been evaluated and deemed adequate to reassess diazinon tolerances. However, additional residue data are required for beans (lima), blueberries, celery, cucumbers, hops, dried peas (IR-4), spinach, sugar beets, and Swiss chard. Tolerances for these commodities will be reassessed once the required data have been submitted and reviewed. Because some of these commodities are representative crops (*) necessary for the establishment of crop group tolerances, crop group tolerances for the following crop groups are dependent on the submission and review of these data: Crop Group (2) Leaves of Root and Tuber Vegetables to cover turnips, sugar beets*, parsnips, carrots, radish, rutabaga, garden beets, and chicory. Crop Group (4) Leafy Vegetables to cover spinach*, parsley, celery*, Swiss chard*, dandelion, lettuce, and endive. Crop Group (9) to cover Cucurbit Vegetables to cover cucumber*, melons, and squash.

For purposes of reregistration, requirements for magnitude of the residue in plants are fulfilled for the following crops: almonds (California use only), apples, beans (snap), brassica leafy vegetables, blackberries, boysenberries, carrots, cherries, corn (sweet), cranberries, figs, grapes, kiwi fruits (tolerance import only), mushrooms, nectarines, peaches, peas (succulent), peppers, plums, onions (dry bulb), pears, peppers (bell), pineapples, potatoes, radish/Chinese radish, squash, strawberries, tomatoes, turnips (roots and tops), walnuts (California use only), and watercress. Adequate field trial data depicting diazinon residues following applications made according to the maximum or proposed use patterns have been submitted for these crops. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted.

IR-4 submitted data to support reassessed tolerances for figs (MRID 44726801) and watercress (MRID 44237101). The tolerance for figs has been reassessed based on the submitted residue data. The registrant can reinstate watercress on the labels or Hawaii can apply for a 24(c) Special Local Need (SLN) for watercress. IR-4 is supporting uses on filberts. They have generated residue field trial data; once these data have been submitted and reviewed, the tolerance for filberts can be reassessed.

Additional data are to be submitted on beans (lima), blueberries, celery, cucumbers, hops, peas (dried), spinach, sugar beets (roots and tops), and Swiss chard. Once residue data on these representative crops has been received and reviewed, sufficient data should be available to support tolerance reassessment for the crops listed above and the following crops: beet tops (garden), chicory, endive, melons, parsley, and squash. Alternatively, once the residue data for the above-listed crops has been submitted and reviewed, if any interested party wishes to support additional crop uses within a crop grouping, sufficient residue data should be available to support crop group tolerances.

The registrant is not supporting uses on the following crops for which tolerances are established: alfalfa, bananas, citrus fruits, clover, coffee, cottonseed, figs, filberts, grasses, olives, peanuts, pecans, sorghum, soybeans, or sugarcane. The Agency is proposing to revoke tolerances for beans, guar, cowpeas, olives, peanuts, pecans, soybeans, and sugarcane, as of January 2000. IR-4 has submitted residue data to support uses on figs, and has expressed interest and generated residue data in support of uses on filberts as noted above. Once it has been determined that no other interested party wishes to support the remaining uses for alfalfa, bananas, citrus fruits, clover, coffee, cottonseed, and grasses these tolerances should be revoked as well.

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for apple, figs, grapes, pineapples, plums, potatoes, sugar beets, and tomatoes. Residues of diazinon did not concentrate in plant processed commodities, with the following exceptions: dried figs (6X). Preliminary data indicate that residues of diazinon may concentrate in dried sugar beet pulp (2X); however, additional residue data on sugar beets reflecting current label rates and PHI are necessary to determine if feed additive tolerances are necessary. Once the residue data are received and reviewed a tolerance may need to be established for sugar beet pulp based on the concentration factor and the highest average field trial (HAFT) residue for sugar beets. A tolerance should be established on dried figs at 0.3 ppm as per the HED Residue Chemistry chapter (Attachment IV).

Regarding the magnitude of the residue for the diazoxon and hydroxy diazinon metabolites, a review of residue field trial data for 25 crops and approximately 2000 samples analyzed for diazinon oxon and hydroxy diazinon indicated the following: for samples treated at the equivalent

of currently-labeled 1X application rates and harvested at the currently-labeled post-harvest intervals (PHIs), all samples showed non-detectable residues (<0.01 ppm) for all crops, except for celery, spinach, and peppers. Hydroxy diazinon was detected in celery after a 1X pre-plant, soil-incorporated application combined with a 1X foliar application up to the post-harvest interval (PHI). Current label rates for celery no longer include the foliar applications close to the time of harvest, but do include a pre-plant, soil-incorporated application. It is anticipated that the new use pattern, may lower detectable residues on harvested celery. Diazinon oxon and hydroxy diazinon residues were detected in spinach at 2% and 1% of the parent compound, respectively. Hydroxy diazinon was detected in peppers at low levels above the detection limit (0.07 ppm) approximately 27% of the parent compound. Foliar application rates for peppers have been lowered 3-fold (3X) from 3.75 lbs ai/A/season to 1.25 lbs ai/A/season on current labels, and the PHI used in the study was 3 days versus the currently-labeled 5 days. It is anticipated that the new use pattern may lower residues on peppers. The summary data for these 3 crops indicated that 1 spinach sample and 4 pepper samples contained detectable metabolite residues. It was unclear how many celery samples (1 or more) were positive for the hydroxy diazinon metabolite.

(v). Residues in Meat, Milk, Poultry, and Eggs

Poultry. Finite residues of diazinon, and its two cholinesterase inhibiting metabolites are not expected in poultry or eggs as a result of residues of diazinon on poultry feed items. A 40 CFR §180.6(a)(3) condition exists and tolerances for poultry tissues and eggs will not be required. A poultry feeding study has been deemed adequate for diazinon, diazoxon, and hydroxydiazinon pending the submission of supporting storage stability data.

Ruminant. Many of the feed items originally used to estimate secondary residues of diazinon in livestock commodities are no longer supported or have been determined not to be significant livestock feed items. As a result of this and a reassessment of existing tolerances for diazinon on ruminant feed items, the maximum theoretical dietary burden for diazinon in ruminants has been revised and is presented below. The theoretical 1X feeding level has been recalculated as 11 ppm and 13 ppm, respectively for dairy and beef cattle. A ruminant feeding study (reviewed and deemed adequate for diazinon, diazoxon, and hydroxy diazinon to support reregistration of diazinon) was conducted at 3 times (40 ppm) to 36 times (400 ppm) these theoretical maximum dietary burden rates. Extrapolating from residues detected at these exaggerated feeding levels to anticipated residues at the maximum theoretical dietary burdens indicate that a 40 CFR §180.6(a)(3) condition exists, and there is no expectation of finite residues of diazinon or its cholinesterase inhibiting metabolites for cattle tissues and milk. As a result tolerances for cattle tissues (meat, meat byproducts, and fat) are recommended for revocation, and a milk tolerance is not required.

The calculated maximum theoretical dietary burdens for livestock are presented below (note that sugar beet tops are not fed to dairy cattle):

Feed Commodity	% Dry Matter ^a	% Diet ^a	Reassessed Tolerance (ppm)	Dietary Contribution (ppm) ^d
Beef Cattle				
Almonds, hulls	90	10	3.0	0.33
Corn forage	48	40	10.0	8.3
Sugar beet pulp	88	20	1.0	0.28
Sugar beet tops	23	10	10.0	4.3
Other	--	20	0	0

Feed Commodity	% Dry Matter ^a	% Diet ^a	Reassessed Tolerance (ppm)	Dietary Contribution (ppm) ^d
TOTAL BURDEN		100		13.3
Dairy Cattle				
Almonds, hulls	90	10	3.0	0.33
Corn forage	48	50	10.0	10.4
Sugar beet pulp	88	20	1.0	0.28
Other	--	20		0
TOTAL BURDEN		100		11.0

^a Table 1 (August 1996).

^b Contribution = [(Reassessed tolerance / fraction DM) X fraction diet].

Summaries of existing studies measuring the magnitude of diazinon residues in sheep tissues after spray applications were considered in reassessing tolerances for sheep tissues required for the use of diazinon on sheep. Results from those studies indicate that existing tolerances of 0.7 ppm in sheep tissues (meat and meat byproducts) are adequate; however, the existing tolerance for diazinon in sheep, fat, should be raised from 0.7 ppm to 5.0 ppm.

(vi). Residues in Water, Fish, and Irrigated Crops

The labels listing uses on cranberries have been revised to include a restriction against using water from irrigated or flooded cranberry bogs or watercress beds to irrigate other crops (except other crops with registered diazinon uses) or for drinking purposes:

"Do not use water from irrigated or flooded cranberry beds for drinking purposes or to irrigate crops other than those appearing on EPA Approved Diazinon labels".

This language should be added to the following existing 24(c) labels specific to cranberry uses: OR900017 and WA900027 (Gowan), WA970001, WI980003, NJ970001, OR970002, and MA970001 (Palette), and WI880009 (Wilber Ellis).

Given this label restriction, OPPTS GLN 860.1400 does not apply to diazinon.

(vii). Residues in Food/Feed Handling Establishments

Labeled uses of diazinon in food and feed handling establishments are listed on the diazinon 4E label. Adequate data are available reflecting the use of diazinon in food handling establishments. The data reviewed in the Reregistration Standard Update indicate that tolerances of 0.02 ppm (2 X the limit of quantitation for the method to account for diazinon and metabolites) should be established for residues in food and feed resulting from use of diazinon in food and feed handling establishments based on non-detectable residues of diazinon, hydroxy diazinon, and diazoxon at 1X and 2X use rates. Labels require that diazinon be applied as a limited spot treatment or a crack and crevice treatment only. Foods must be removed and/or covered during application. Based on data submitted to support the food additive petition (180.153(a)(2) & (3)) and associated label restrictions on commercial applicators applying diazinon in food/feed handling establishments, there is no likelihood of detectable residues [Limit of Detection (LOD) is 0.01 ppm] on food/feed provided label directions are followed.

Although the establishment of a tolerance is necessary because use in food/feed handling establishments is considered a food use, it is not necessary to include this use in the dietary risk assessment. Because residues were non-detectable (<0.01 ppm) for diazinon, hydroxy diazinon,

and diazoxon as a result of a 1X and 2X labeled application rate in food/feed handling establishments, it is recommended that the dietary risk assessment for diazinon be conducted including potential residues from the food/feed handling establishment use at ¼ the limit of detection (0.0025 ppm or ½ LOD extrapolated to 1x use rate) for diazinon, hydroxy diazinon, and diazoxon, each, and assuming the non-detectable residues are zero (as per TRAC Science Policy paper entitled, “Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments”, draft 11/30/98).

(viii). Confined Accumulation in Rotational Crops

An adequate confined rotational crop study is available. These data indicate that residues of diazinon in rotational crops are qualitatively similar to the residues resulting from the direct application of diazinon to the primary crops. Based on the results of this study, limited field rotational crop studies are required. The registrant has agreed to conduct limited field rotational studies on representative crops.

(ix). Anticipated Residues and/or Monitoring Data and Percent Crop-Treated

HED's current dietary exposure assessment for diazinon is provided below under section b. Dietary Risk Characterization - Food Sources. Specific anticipated residues used for each food commodity included in this assessment are provided in Attachment V (Diazinon: Acute and Chronic Dietary Risk Assessment) but are described briefly here. The anticipated residues in this assessment are based on the following sources, in order of preference: USDA PDP monitoring data, FDA surveillance monitoring data, and controlled field trial data. The monitoring data are preferred over field trial data because samples are more reflective of residues that may occur on foods as consumed. The PDP data are preferred because, in general, more samples are taken, and the sampling protocols have been designed to reflect variations in consumption patterns throughout the year and geographically. PDP samples include both domestic and imported foods.

The USDA Pesticide Data Program (PDP) has surveyed pesticide residues in selected food items since 1991. Final data are available for diazinon up through 1997. In this assessment we have considered these final data, as well as, preliminary data from the years 1998 and 1999. The PDP program has reported analyses for diazinon *per se* for almost all commodities up through 1998. The preliminary 1999 data include analyses for the diazinon oxon for single servings of apples, as well as, composited samples of apples, peppers, spinach, strawberries, and tomatoes. For the 1997 data, out of 11 crops and more than 7000 samples analyzed, no detectable diazinon oxon residues were reported with the exception of 1 spinach sample that contained residues at 50% of the parent compound. Although not normally included in the analyses, an unidentified chromatogram peak was investigated on 1 spinach sample and was determined to be the oxon of diazinon. The preliminary 1998-1999 data on 5 crops (apples, peppers, spinach, strawberries, and tomatoes) show no detectable diazinon oxon residues in any of the more than 1400 samples analyzed. FDA monitoring data for diazinon and the hydroxy and oxon metabolites of concern were considered for the years 1992 through 1998. There were no reports of detectable residues of the metabolites of diazinon for these years either in domestic or imported foods.

The HED MARC suggested including diazoxon and hydroxy diazinon in dietary risk assessments if they were found to be present or if their concentration levels could be estimated in foods. However, based on the above PDP and FDA monitoring data, a review of field trial data in which detections of either metabolite were sporadic (see section (3)(a)(i)), and results from 5 metabolism studies in which neither hydroxy diazinon nor diazinon oxon were found (see section (3)(a)(iv)),

concentrations of these 2 metabolites were assumed to be zero in the dietary assessments. The preponderance of residue data from metabolism studies, residue field trials and monitoring data (USDA's PDP and FDA Surveillance Monitoring data) indicate that these two metabolites are infrequently to never detected for the majority of crops analyzed for diazinon oxon and hydroxy diazinon. If there is a concern regarding how the metabolites were handled in the dietary assessments, HED could revise the current dietary assessments to include the residues of these compounds where warranted on a crop-specific basis, but there appears to be no cogent rationale for including these metabolites in all crops at some default value in light of the available residue data. HED does not recommend assuming ½ the limit of detection values for both metabolites across all crops. HED believes this would result in an overly conservative assessment driven by these default ½ LOD values because of the relatively low levels of diazinon, *per se*.

Residue data from PDP were decomposited for the following crops to obtain, initially, 1000 residue values, which were later truncated at the tolerances of their respective crops prior to incorporation into the acute dietary analysis: carrots, peaches, apples, celery and head lettuce. The residue values generated by decomposition were also extended (translated) to crops with unavailable or insufficient residue data. Accordingly, data for carrots were translated to turnip-roots, rutabagas, and parsnips; data for peaches were translated to apricots and nectarines, and data for celery were translated to Swiss chard. In cases where monitoring data were translated to similar commodities, this was done in accordance with guidance found in HED SOP 99.3 for Translation of Monitoring Data (March 26, 1999). For those cases in which field trial data were used, the anticipated residues were based on the maximum supported use patterns, as summarized in the RED. If neither adequate monitoring data or information on supported use patterns were available, then residues were assumed to be at the tolerance level (see Table 4).

Table 4. Diazinon: Translation of Pesticide Monitoring Data.		
Commodity Analyzed	Source of Data	Commodity Translated to
Peach	PDP	Apricot, Nectarine
Spinach	PDP	Garden Beet tops, Turnip tops, Parsley, Dandelion
Blackberry/Raspberry	FDA	Other Caneberries
Orange*	PDP	Other Citrus*
Orange Juice*	PDP	Other Citrus Juice*
Carrots	PDP	Parsnip, Rutabaga, Turnip root, Ginseng
Garden Beet Roots	FDA	Sugar Beets
Celery	PDP	Swiss Chard
Collards, Kale, Mustard Greens combined	FDA	Combined residue data used
Lettuce	PDP	Radicchio
Bok choy	FDA	Chinese broccoli
Broccoli	FDA	Brussels sprouts
Cauliflower	FDA	Kohlrabi
Green Onions*	FDA	Leeks*
Bulb Onions	FDA	Shallots, Garlic

Table 4. Diazinon: Translation of Pesticide Monitoring Data.		
Commodity Analyzed	Source of Data	Commodity Translated to
Green Peppers	FDA	Other peppers Hot Peppers
Cantaloupe	FDA	Casaba, Crenshaw, Honeydew, Persian Melon, Balsam Pear, Bitter Melon, Wintermelon
Green Beans	PDP	All Succulent Beans, Succulent Blackeyed Peas
Bananas*	PDP	Plantain*
Radish and Oriental Radish combined	FDA	Oriental Radish
Wheat Grain	PDP	Sorghum

* Crops/commodities with an asterisk are no longer supported by the registrant. However, because these commodities have tolerances, they have been included in the dietary risk assessments. Once it has been determined that no other interested party wishes to support these uses, the tolerances can be recommended for revocation, and these commodities removed from the dietary assessments.

Percent Crop Treated Data

A quantitative usage analysis for diazinon was provided by BEAD based on data years 1987-96 (Alan Halvorson, QUA date: January 29, 1999) and is included in Attachment V. Data sources included USDA/NASS (1990-97), California EPA, Department of Pesticide Regulation (1993-95), National Center for Food and Agricultural Policy, and various proprietary data sources (1987-97). The weighted average of the percent of crop treated was used for estimating chronic dietary exposure and an estimated maximum of the percent of crop treated was used for estimating acute dietary exposure. Percent crop treated information was used either as a predictor of the probability of residues occurring on a given monitoring sample as in the acute dietary assessment or, as in the case of blended commodities and for chronic exposure, as an adjustment factor to the average residue occurring in a commodity. For some of the PDP commodities, imported samples comprise a significant portion of the database. For those commodities, the percent crop treated information provided by BEAD was adjusted to account for imports. The assumption was made that for those commodities consumed solely from imports, 100% of the crop had been treated. Note: This is a non-standard HED assumption and can be refined once information on the percentage of imported crops treated with diazinon are made available.

Processing Factors

All processing factors used in this assessment are summarized in Table 5. These factors are input into the DEEM software as adjustment factor #1 (see printouts of DEEM inputs in attachment V).

Table 5. Diazinon Processing Factors Summary			
Category	Processing Factor used for current analysis	Data Sources	Comments and Agency Reviews
Apples-dried	8	DEEM Default	
Apples-juice/cider	1		Monitoring data used for juice
Apples-juice-concentrate	3	Ratio of Default factors for juice & concentrate	Conc. factor applied to juice data
Apricots-dried	6	DEEM Default	
Bananas-dried*	3.9	DEEM Default	

Table 5. Diazinon Processing Factors Summary			
Category	Processing Factor used for current analysis	Data Sources	Comments and Agency Reviews
Cherries-dried	4	DEEM Default	
Cherries-juice	1.5	DEEM Default	
Cottonseed meal*	0.44	MRID 00032881	S. Funk, 4/17/92 used average factor from all studies with detectable residues
Cottonseed Oil*	2.2	MRID 00032881	S. Funk, 4/17/92 used average factor from all studies with detectable residues
Cranberries-juice	1.1	DEEM Default	
Cranberries-juice-concentrate	3.3	DEEM Default	
Grapefruit-juice*	1		Used orange juice monitoring data
Grapefruit-juice-concentrate*	3.9	Ratio of Default factors for juice & concentrate	Factor applied to orange juice monitoring data
Grapes-juice	1	MRID 41410001	A factor of 0.02 for juice had been demonstrated S. Funk, 4/17/92 Don't use factor because juice data are available
Grapes-juice-concentrate	3	Ratio of Default factors for juice & concentrate	
Grapes-raisins	0.13	MRID 41410001	S. Funk, 4/17/92 used average factor from all studies with detectable residues
Lemons-juice*	1		Used orange juice monitoring data
Lemons-juice-concentrate*	5.7	Ratio of Default factors for juice & concentrate	Factor applied to orange juice monitoring data
Limes-juice*	1		Used orange juice monitoring data
Limes-juice-concentrate*	3	Ratio of Default factors for juice & concentrate	Factor applied to orange juice monitoring data
Onions-dehydrated or dried	9	DEEM Default	
Oranges-juice*	1		Used orange juice monitoring data
Oranges-juice-concentrate*	3.7	Ratio of Default factors for juice & concentrate	Factor applied to orange juice monitoring data
Peaches-dried	7	DEEM Default	
Pears-dried	6.25	DEEM Default	
Pineapples-dried	5	DEEM Default	
Pineapples-juice	0.12	MRID 42179501	P. Deschamp, 6/3/92, D174774
Pineapples-juice-concentrate	0.44	MRID 42179501	(juice factor) *(ratio of DEEM defaults for juice & concentrate)
Plantains-dried	3.9	DEEM Default	
Plums/prunes-juice	1.4	DEEM Default	
Plums/prunes-dried	0.6	MRID 43274401	S. Funk, 5/24/93, D189573

Table 5. Diazinon Processing Factors Summary			
Category	Processing Factor used for current analysis	Data Sources	Comments and Agency Reviews
Potatoes/white-dry	6.5	DEEM Default	
Sugar-beet-molasses	0.5	MRID 41336514	Diazinon Reg. Std. Update, 1/24/92
Tangerines-juice*	1		Used orange juice monitoring data
Tangerines-juice-concentrate*	3.2	Ratio of Default factors for juice & concentrate	Factor applied to orange juice monitoring data
Tomatoes-catsup	0.30	MRID 41336508	S. Funk, 4/17/92 used average factor from all studies with detectable residues
Tomatoes-dried	14.3	DEEM Default	
Tomatoes-juice	0.05	MRID 41336508	S. Funk, 4/17/92 used average factor from all studies with detectable residues
Tomatoes-paste	0.60	MRID 41336508	S. Funk, 4/17/92 used average factor from all studies with detectable residues
Tomatoes-puree	0.70	MRID 41336508	S. Funk, 4/17/92 used average factor from all studies with detectable residues

* Crops/commodities with an asterisk are no longer supported by the registrant. However, because these commodities have tolerances, they have been included in the dietary risk assessments. Once it has been determined that no other interested party wishes to support these uses, the tolerances can be recommended for revocation, and these commodities removed from the dietary assessments.

Dietary exposure assessment

The following commodities, for which all uses have been canceled and tolerance revocations have been recommended, are not included in the current assessment:

- olives
- peanuts
- pecans
- soybeans
- sugarcane
- beans, guar
- cowpeas

The potential for transfer of residues to meat, milk, poultry and eggs from animal feeds has been reassessed. It has been determined that measurable secondary residues in these commodities are not likely. Dermal treatments are not being supported for any livestock or poultry except sheep. Therefore, the following commodities are not included in the current assessment:

- milk
- all poultry meats and meat byproducts
- eggs
- all livestock meats and meat byproducts except for those of sheep

Uses of diazinon on the following crops are not being supported by the registrant; however, they are included in the present assessment because of their existing tolerances and pending a determination of whether any other interested party wishes to support them.

- citrus fruits
- coffee
- cotton
- bananas
- sorghum

Tolerance level residues were assumed to be present in coffee and cottonseed. The registrant is not supporting uses on alfalfa but tolerances are established for forage (40 ppm) and hay (10 ppm). The only alfalfa food commodity is alfalfa sprouts. This commodity is not being considered in the present assessment because, in our judgement, there is little likelihood for use of diazinon on alfalfa grown for sprouts or from dietary exposure to diazinon via consumption of sprouts.

Anticipated residues were derived in accordance with established Agency policies and guidance for chronic and acute dietary exposure assessments. Residues for chronic analysis are generally based on the mean of the best available residue data with appropriate adjustments for percent crop treated and residue concentration/reduction from processing. Acute anticipated residues were derived using guidance provided in HED SOP 99.6 (Classification of Food Forms with Respect to Level of Blending (8/20/99)). Each food form entered in the DEEM software for dietary exposure assessments is classified as being blended (B), partially blended (PB), or not blended (NB). As more extensively described in the SOP, PDP, and FDA monitoring data, which are generally based on composite samples, may be used to construct residue distributions for input into a Monte Carlo analysis using the DEEM software. If foods are blended (B or PB) the entire distribution of monitoring data can be used to represent a distribution. If the foods are classified as not blended (NB) then further evaluation of PDP and FDA data are required before compiling a residue distribution. The composited samples from PDP and FDA (5 to 20 lbs) may not reflect residue levels in single-serving commodities. Thus, these monitoring data should be "decomposed" via a suitable statistical procedure in order to simulate a distribution of single serving commodities. In the current analysis, we are using a procedure developed by HED (Allender, H. "Use of the Pesticide Data Program (PDP) in Acute Dietary Assessment," EPA interim guidelines, August 1998). At present our decomposing procedure requires that the available monitoring data contain at least 30 detects. If fewer than 30 detects occur then a judgement is made as to whether the composite data set may be used either directly or with an appropriate multiplication factor. These considerations are also discussed at length in HED SOP 99.6. In the current assessment, we have applied some criteria to using the available composite monitoring data for foods that are not blended. The criteria and assumptions involved are as follows:

- Any tolerance-exceeding residues in the monitoring data are considered to exist because of off-label uses, and are excluded from the anticipated residues, which are intended to represent good agricultural practices.
- If monitoring data for a not-blended food contain enough detectable residues (~30 or more), then the data are decomposed with the Allender method. This method produces a lognormal distribution of residue values that is used in a Monte Carlo analysis.
- The lognormal distribution obtained by the Allender method is truncated at the tolerance

level for the commodity of interest. Although tolerances are also based on composite samples, these are from controlled field trials in which it is assumed that all components of the composite have been treated with the maximum allowable level of diazinon. Therefore, it is assumed that the tolerance, which is based on a rounded up maximum residue value from field trials, would not be exceeded in single servings, if good agricultural practices are followed.

- If significantly fewer than 30 detectable residues occur in the monitoring data, then the Allender method is not used. If the monitoring data contain very low residues then they are used directly with the assumption that residue levels could not be underestimated significantly. If some of the residues are significantly higher than the LOD of the analytical method, then a multiplication factor is applied to the detected residues as a conservative simulation of residues that may occur in single servings within a given composite sample. This factor is derived as follows: The tolerance for the commodity of interest is divided by the highest residue level reported. All detects for that commodity are multiplied by this factor and the adjusted data are used directly to construct a residue distribution for Monte Carlo analysis.

(x.) Consumption Data

The acute module version 6.78 and the chronic module version 6.76 of DEEM™ were used for these exposure assessments. Consumption of the various commodities was estimated from the 1989 - 1992 USDA *Continuing Surveys of Food Intake for Individuals*.

b. Dietary Risk Characterization - Food sources

(i). Acute Dietary (Food) Exposure and Risk Estimates

The estimate of acute dietary exposure from uses of Diazinon on food/feed crops and animals is summarized in Table 6. The DEEM inputs and complete acute dietary analysis are appended to this document in Attachment V. As per OPP policy, a reference dose (RfD) modified by an FQPA safety factor is referred to as a population-adjusted dose (PAD). Because the FQPA safety factor was reduced to 1x for diazinon, the acute RfD is equal to the acute PAD. For the groups listed in Table 6, the estimated exposures at the 99.9th percentile of exposure ranged from 0.000667 mg/kg body weight/day (27% aPAD) for children 7 to 12 years old to 0.00159 mg/kg body weight/day (64% aPAD) for the most highly-exposed subgroup: non-Hispanics/non-white/non-black. This subgroup includes: Asians/Pacific Islanders/American Indians/Alaskan Natives, or some other race.

Table 6. Acute Dietary Exposure Results for Diazinon Including Sheep Commodities*				
Total Exposure by Population Subgroup				
Population Subgroup	Total Exposure @ 99 th Percentile		Total Exposure @ 99.9th Percentile	
	mg/kg body wt/day	Percent of aPAD	mg/kg body wt/day	Percent of aPAD
U.S. Population (total)	0.000191	7.6%	0.000883	35.3%
Non-Hispanic/non-white/non-black	0.000505	20.2%	0.00159	63.7%
Nursing infants (< 1 year)	0.000230	9.2%	0.000759	30.4%

Table 6. Acute Dietary Exposure Results for Diazinon Including Sheep Commodities*				
Total Exposure by Population Subgroup				
Population Subgroup	Total Exposure @ 99 th Percentile		Total Exposure @ 99.9 th Percentile	
	mg/kg body wt/day	Percent of aPAD	mg/kg body wt/day	Percent of aPAD
All infants (< 1 year)	0.000243	9.7%	0.000697	27.9%
Children 1-6 yrs	0.000334	13.4%	0.00150	60.2%
Children 7-12 yrs	0.000181	7.2%	0.000667	26.7%
Females 13+ (pregnant not nursing)	0.000158	6.3%	0.000942	37.7%

* Results do not include sugarcane use under 24(c) SLN LA96001000.

Critical Commodity Analysis

An analysis of commodities contributing most highly to acute dietary exposure to diazinon for the most highly exposed subgroup indicated that sheep commodities (fat and lean meat) were the major contributors to high exposure events in the Monte Carlo analysis. It should be noted that the anticipated residues for these commodities are conservative. The maximum reported residues in fat and lean meat from dermal uses were used in the dietary analyses. The maximum residue value for sheep fat (2.2 ppm) and for lean meat (0.13 ppm) have been adjusted for percent of sheep-treated with diazinon sprays (37%). However, these values are not considered to be highly refined, but were the best available. The residue values are based on a series of controlled dermal treatment studies and represent residues at the 1x label rate with a 3-day or less pre-slaughter interval. These residue values were multiplied by 37% to account roughly for the percentage of sheep-treated with diazinon. The percentage used reflects partial knowledge of the percentage of domestic sheep consumed (65%) and the number of domestic sheep treated with diazinon (3%), and the percentage of imported sheep consumed (35%) and the assumption that all imported sheep are treated with diazinon (100%). The resulting factor, 37%, was used to modify the maximum residue values for sheep commodities in DEEM. HED notes that the assumption that 3% of domestic sheep and 100% of imported sheep are treated with diazinon is likely to be conservative and may overestimate the resultant exposures. Further refinements to the estimates of sheep-treated with diazinon, domestic and imported, should reduce dietary risk estimates.

Once sheep commodities are removed from the dietary analysis, all risk estimates at the 99.9th percentile of exposure are below 50% of the aPAD. The contribution of sheep commodities to the appearance of higher dietary risk was demonstrated by a second Monte Carlo analysis in which sheep commodities were excluded from the analysis. These results are summarized below in Table 7 and the DEEM analysis is appended as Attachment V. The estimated acute dietary exposure dropped significantly for those consumers that would be expected to eat sheep. For the non-Hispanic-other group, the exposure at the 99.9th percentile dropped from 64 % aPAD to 35% aPAD. Overall, for the subgroups listed below in Table 7, the exposure ranged from about 24% aPAD for children 7 to 12 years old to about 48% aPAD for children 1 to 6 years old. Note that in this analysis, the effect of excluding sheep commodities from the diet mostly affects one or two subgroups.

Table 7. Acute Dietary Exposure Results for Diazinon Excluding Sheep Commodities.*				
Total Exposure by Population Subgroup				
Population Subgroup	Total Exposure @ 99 th Percentile		Total Exposure @ 99.9 th Percentile	
	mg/kg body wt/day	Percent of aPAD	mg/kg body wt/day	Percent of aPAD
U.S. Population (total)	0.000167	6.7%	0.000660	26.4%
Non-Hispanic/non-white/non-black (other)	0.000203	8.1%	0.000882	35.3%
All infants (< 1 year)	0.000225	9.0%	0.000677	27.1%
Nursing infants (< 1 year)	0.000234	9.4%	0.000756	30.2%
Children 1-6 yrs	0.000299	12.0%	0.00121	48.4%
Children 7-12 yrs	0.000171	6.8%	0.000600	24%
Females 20+ (not pregnant/not nursing)	0.000160	6.4%	0.000697	27.9%

* Results do not include sugarcane use under 24(c) SLN LA96001000.

(ii). Chronic Dietary (Food) Exposure and Risk Estimates

As per OPP policy, a reference dose (RfD) modified by an FQPA safety factor is referred to as a population-adjusted dose (PAD). Because the FQPA safety factor was removed for diazinon, the chronic RfD is equal to the chronic PAD. Risk estimates for all subgroups analyzed were less than 100% of the chronic population-adjusted dose (cPAD) and therefore risk estimates for all subgroups are below HED's level of concern. The estimate of chronic dietary exposure and risk for seven most-highly exposed subgroups of interest from uses of diazinon on food/feed crops and animals is summarized in Table 8. The dietary exposure model inputs and complete chronic analysis are appended to Attachment V. For the most-highly exposed subgroup (non-Hispanic/non-white/non-black) the major contributors to the estimated exposure were sheep meat and fat (16.5% of cPAD), mushrooms (2.9% of cPAD), coffee (2.2% of cPAD), and orange juice concentrate (1.1% of cPAD). The highest contributors to estimated chronic exposure for all infants less than 1 year old were bananas (1.78% of cPAD), pineapples (1.25% of cPAD), apple juice concentrate (0.91% of cPAD), orange juice concentrate (0.86% of cPAD), and pear juice (0.75% of cPAD). For children 1 to 6 years old the highest contributors were mushrooms (2.55% of cPAD), sheep meat and fat (1.9% of cPAD), orange juice concentrate (1.74% of cPAD), apple juice (1.11% of cPAD), and bananas (1.1% of cPAD).

This analysis, as in the acute dietary analysis, also assumed maximum residues for sheep commodities, and that 3% of the domestically-consumed sheep and 100% of imported sheep are treated with diazinon. Although an analysis excluding sheep commodities was not conducted for the chronic analysis, the same results as seen in the acute dietary analysis are expected, i.e., with the exclusion of sheep commodities from the dietary analysis, risk estimates will be lowered. [Note: For the purposes of this refined exposure and risk analysis, food/feed handling establishment uses were excluded from this chronic dietary assessment. For an explanation and the results of including these uses, see the discussion below.]

Table 8. Chronic Dietary Exposure Results for Diazinon*		
Total Exposure by Population Subgroup		
Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of cPAD
U.S. Population (total)	0.000019	9.6%
Non-Hispanic/non-white/non-black (other)	0.000033	16.5%
All infants (< 1 year)	0.000020	9.8%
Non-nursing infants	0.000022	10.8%
Children 1-6 yrs	0.000027	13.3%
Children 7-12 yrs	0.000016	8.0%
Females 13+ (nursing)	0.000024	12.1%

* Results do not include sugarcane use under 24(c) SLN LA96001000.

Food Handling Establishment Uses

Diazinon food handling establishment tolerances are being recommended; therefore, a discussion of the dietary risk from such uses is included. These uses could have been included in the chronic dietary assessment; however, there is little basis for conducting such an assessment other than exercising a judgement based on knowledge of the properties of diazinon and the nature of its uses in food handling areas. The use directions on diazinon labels are very detailed and designed to avoid any contact with foods. HED concludes with respect to food/feed handling establishment uses that it is unlikely that any residues of diazinon will occur on foods from these uses as long as it is used according to the label. Nevertheless, HED conducted a chronic dietary exposure and risk analysis which included food/feed handling establishment uses and may be useful for approximating a worst-case scenario. The only quantitative data available for such an assessment is a residue study conducted at twice the label rate in a food handling establishment. Residues were non-detectable (<0.01 ppm) on a variety of foods exposed in this test.

For the purposes of a very conservative assessment, a residue on 100% of exposed food was assumed to be 0.0025 ppm ($\frac{1}{2}$ LOD extrapolated to 1x use rate or $\frac{1}{4}$ of the LOD). No information on what percent of food handling establishments may actually be treated with diazinon was available, so the assumption was made that all food consumed comes from treated establishments. The value of 0.0025 ppm was input into all food forms, except water, in a dietary analysis, and all default concentration factors were removed. The results ranged from a low of 0.000034 mg/kg body wt/day (17% of cPAD) for females over 20 years (not pregnant or nursing) to a high of 0.000142 mg/kg body wt/day (71% of cPAD) for children between 1 and 6 years old. The exposure for the total U. S. Population was 0.000051 mg/kg body wt/day (26% of cPAD). As can be deduced from the results of this exercise, exposure to diazinon accounts for less than 100% of the cPAD (71% of cPAD for food-handling uses plus 13% of cPAD for the remaining dietary exposures for children 1 to 6) even with residues included in the chronic dietary assessment at 0.0025 ppm ($\frac{1}{4}$ LOD) for all foods to cover food-handling establishment uses. However, in order to estimate a reasonable, worst-case exposure from this exercise, one needs much more data than currently available. The actual usage of diazinon in all types of food handling establishments (the percentage of establishments receiving diazinon treatments) would have to be considered at the least.

c. Dietary Exposure - Drinking Water

The EPA's Office of Water has established an adult lifetime Health Advisory (HAL) for diazinon of 0.6 ug/L, but has not established a Maximum Contaminant Level (MCL). Environmental fate data indicate that diazinon may occur in both ground water and surface waters to varying degrees. Diazinon is only moderately mobile and persistent. Laboratory data indicate that diazinon will not persist in acidic water; however, in neutral and alkaline waters, residues may be quite persistent. Oxydimethylphosphoramide is the main soil and water degradate. EFED reports that based on environmental fate study data, two hydroxy pyrimidine compounds (both lacking the organophosphate moiety) have been recovered from soil, groundwater, and surface water. Most monitoring efforts to date for diazinon in surface and groundwater have included the parent compound only, and there was no mention of the likelihood of detecting hydroxy diazinon or the diazinon oxon in water in the drinking water assessment (Attachment VII). The HED Metabolism Assessment Review Committee (MARC) concluded that focusing on diazinon, *per se*, in water should be adequate for the purposes of risk assessment. This decision included consideration of the likelihood of occurrence in water of major soil and water metabolites that are toxicologically significant (HED MARC memorandum from D. Hrady to G. Kramer dated 4/17/98).

Currently, HED uses drinking water levels of comparison (DWLOCs) as a surrogate to capture risk associated with exposure to pesticides in drinking water in accordance with HED SOP 99.5. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). It is used as a point of comparison against the model estimates to determine if the estimated concentration is of concern. A DWLOC may vary with drinking water consumption patterns and body weights for specific subpopulations. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from the DEEM™ analysis) was subtracted from the acute PAD to obtain the acceptable acute exposure to diazinon in drinking water. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM™) plus any potential chronic residential exposures was subtracted from the chronic PAD to obtain the acceptable chronic (non-cancer) exposure to diazinon in drinking water. DWLOC values were calculated using default body weights and consumption values (70 kg for adult males, 60 kg for adult females, and 10 kg for children, and drinking water consumption figures of 2 L/day for adults and 1 L/day for children). HED has calculated drinking water levels of comparison for acute and chronic exposures to diazinon in drinking water for the following subgroups: general U.S. population, non-Hispanic/ non-white/non-black, females (13+ or 20+), children (1-6 years old), and all infants (<1 year old), respectively. A comparison of DWLOC values for acute and chronic risk to estimated concentrations of diazinon in ground and surface waters is given in Tables 19 and 20 below. Example DWLOC calculations are also provided in the section below.

i. Groundwater (modeling/monitoring)

EFED summarized the results from a variety of ground water monitoring studies that included diazinon as an analyte. No metabolites were included in the analyses. The results of some of these studies are briefly outlined here. For a full discussion of the water quality data used, please see Attachment VII, EFED memorandum dated 5/11/99 from R. Matzner to C. Eiden for complete details. In general, diazinon has been detected in ground water from a variety of sources, drinking water wells, monitoring wells, and agricultural wells. Many of the studies conducted have been located in areas where pesticide use and agricultural production are considered to be high. However, the studies have not been targeted explicitly to diazinon use patterns, *per se*. Summary

statistics were included for each sampling study conducted. For each study, range, mean, median, and 95th percentile values were determined from all samples analyzed including non-detects which were given a value of ½ the limit of detection. Based on the data presented in the EFED memorandum, the concentrations of diazinon detected in ground water (all wells) were low, ranging from non-detectable (ND) to 1.0 ug/L.

Much of the groundwater data provided comes from the USGS National Water Quality Assessment Program (NAWQA), which assesses ambient water quality. Approximately 2% of the groundwater samples collected through this program from 1992 to 1996 had positive detections of diazinon. The maximum concentration detected in ground water from the NAWQA study was 0.085 ug/L, 95th percentile concentration values were ND for all wells sampled, and the median value was ND or < 0.002 ug/L. Results from the NAWQA database indicate that diazinon was detected more frequently in shallow ground water in urban areas than in agricultural areas. The results of the NAWQA data for ambient groundwater and surface water are discussed in more detail below.

The relative percentage of samples with detections to total wells sampled from studies in which rural drinking water wells were sampled ranged from 5 to 22.5%. The maximum concentration detected in the rural drinking water wells sampled was 1.0 ug/L, and the 95th percentile concentration values ranged from <0.01 (ND) to <0.3 ug/L depending on the study (see summary data below). Average (mean) concentrations as determined from all samples analyzed were reported to range from 0.012 to <0.3 ug/L. Since most wells were sampled one time only, an average concentration value for diazinon per well is not available.

EFED also used the SCI-GROW model to provide a 90-day average concentration as an upper bound estimate of diazinon concentrations in shallow ground water. That estimate, 0.8 ug/L, compares favorably with the 95th percentile value of the maximum concentration values of diazinon in ground water (0.9 ug/L). However, EFED recommended the upper bound, 95th percentile value (0.9 ug/L) from drinking water well monitoring data for use in acute and chronic risk assessments. See aforementioned EFED memorandum for details on the model estimate.

Ambient Ground Water Quality

USGS (NAWQA) samples ground water from a variety of sources including newly drilled monitoring wells, production wells (domestic and public-supply wells), springs and tile drains. The USGS generated statistical summaries of the ground water data for all wells sampled, shallow wells sampled, and major aquifer sampled. Data from the shallow wells was characterized as ground water in primarily agricultural areas or in primarily urban areas. The data summarized below in Tables 9-11 were collected from 6/30/92 to 11/15/96. The limit of detection for diazinon was 0.002 ug/L and no metabolites were included in the analyses. No delineation as to which of the wells sampled, if any, were used for drinking water versus other uses was provided.

Table 9. Results for Diazinon (ug/L) from USGS NAWQA monitoring program for all wells sampled ¹ .						
Wells	Samples	Detects *	Range	Mean	95 th Percentile	Median
2616	3023	51(1.7%)	0.160-ND	0.014	ND	ND

¹ Range, mean, median and 95th percentile values determined from all samples. Samples below the detection limit (LOD) were given a value of ½ the LOD.

* Percentage detects/number of samples.

The agricultural and urban land-use categories in Table 10 were represented by wells chosen or designed to sample shallow, recently recharged ground water to determine the effects of specific land uses on water quality.

Table 10. Results for Diazinon (ug/L) from USGS NAWQA monitoring program for shallow wells sampled ¹ .							
Land Use	Wells	Samples	Detects *	Range	Mean	95 th Percentile	Median
Urban	301	301	5 (1.7%)	0.010-ND	NR ²	ND	NR ²
Agricultural	924	924	5 (0.5%)	0.077	NR	ND	NR

¹ Range, mean, median and 95th percentile values determined from all samples. Samples below the detection limit (LOD) were given a value of ½ the LOD.

² Not reported.

* Percentage detects/number of wells.

Sites comprising the "major aquifers" category in Table 11 had no such restrictions on land use or water age, and thus, represent a broader mixture of land uses and ground water depths.

Table 11. Results for Diazinon (ug/L) from USGS NAWQA monitoring program for major aquifers sampled ¹ .						
Wells	Samples	Detects *	Range	Mean	95 th Percentile	Median
933	933	17 (1.8%)	0.085-ND	NR ²	ND	NR ²

¹ Range, mean, median and 95th percentile values determined from all samples. Samples below the detection limit (LOD) were given a value of ½ the LOD.

² Not reported.

* Percentage detects/number of wells.

Drinking Water Wells

The EPA's National Pesticide Survey (NPS) was designed to determine the frequency of pesticide and nitrate-nitrogen contamination in ground water by sampling community water systems and rural drinking water wells nationwide. A total of 1349 wells were sampled (783 rural domestic wells and 566 community water system wells) were selected based on a random, stratified design and sampled once. Drinking water wells were stratified by location relative to general agricultural use (ranked as high, medium, and low) as opposed to specific compound use and relative vulnerability to ground water contamination. Diazinon was included as an analyte in the survey; however, no diazinon was detected in any sample at a limit of detection of 1.1 ug/L.

Although limited in scope, there were some studies designed to determine the quality of drinking water in an area associated with agricultural uses or designed to sample drinking water (households, community water system and/or rural wells). The results of these studies are outlined below. For details see EFED memorandum previously cited. No metabolites were included in any of the studies' analyses.

A survey of household drinking water supplies from ground-water sources was conducted in Page, Rappahannock and Warren counties in the State of Virginia in 1989 and 1990. Agricultural production in these counties includes fruit trees, cattle, poultry and grains. The area's geology is predominantly shale and limestone with karst topography (limestone outcroppings and sinkholes). One sample from each well was collected by the homeowners as close as possible to the well. The wells selected were considered to be at high risk for contamination based on general water

chemistry (high nitrates and chloride concentrations) and proximity to agricultural activities that could contaminate the supply. Wells averaged 200 feet in depth and the limit of detection for the analysis of diazinon was 0.01 ug/L. The results are provided in Table 12.

Table 12. Results from household drinking water study in Virginia for diazinon in ug/L. ¹							
County	Wells	Samples	Detects *	Range	Mean	95 th Percentile	Median
Page	60	60	6 (10%)	0.103-ND	0.012	0.075	ND
Rappahannock	40	40	9 (22.5%)	0.262-ND	0.023	0.086	ND
Warren	26	26	0	NA	NA ²	NA	NA

¹ Range, mean, median and 95th percentile values determined from all samples. Samples below the detection limit (LOD) were given a value of ½ the LOD.

² Not applicable.

* Percentage detects/number of wells.

Results from a ground-water monitoring study conducted in eight regions of Missouri to determine the quality of drinking water in agricultural areas are presented below in Table 13. Twenty-five wells in 8 regions (201 wells) were sampled 4 times each (804 samples). Monitoring was conducted quarterly from December 1987 to September 1989 at each well. Five samples were positive for diazinon. Four of the five samples with positive detections were from samples collected in December 1987, and one was from a March 1988 sampling. Diazinon use was documented (354 pounds of active ingredient) in six of the eight regions sampled. Two of these regions had positive detections of diazinon. The limit of detection was 0.3 ug/L.

Table 13. Results from ground-water monitoring study in Missouri for diazinon in ug/L. ¹						
Wells	Samples	Detects *	Range	Mean	95 th Percentile	Median
201	804	5 (2%)	1.0-ND	ND	ND	ND

¹ Range, mean, median and 95th percentile values determined from all samples. Samples below the detection limit (LOD) were given a value of ½ the LOD.

* Percentage detects/number of wells.

Results from a study to sample wells from 10 counties in the Mississippi Delta from March 1983 to February 1984 are presented below in Table 14. Wells sampled were 40 to 70 feet in depth and selected based on their location in areas with high pesticide usage and agricultural production. The limit of detection was 0.01 ug/L.

Table 14. Results from ground-water monitoring study in Mississippi for diazinon in ug/L. ¹						
Wells	Samples	Detects *	Range	Mean	95 th Percentile	Median
143	143	7 (5%)	0.478-ND	0.013	ND	ND

¹ Range, mean, median and 95th percentile values determined from all samples. Samples below the detection limit (LOD) were given a value of ½ the LOD.

* Percentage detects/number of wells.

ii. Surface water (modeling/monitoring)

EFED summarized the results from a variety of surface water monitoring studies that included diazinon as an analyte conducted by the USGS under the NAWQA and Stream Water Quality Network (NASQAN) programs, California state regulatory agencies, and individuals in their

memorandum dated 5/11/99 from R. Matzner to C. Eiden. The results of some of these studies are briefly outlined here. For a full discussion of the water quality data used, please see Attachment VII (EFED memorandum), for complete details. In general, diazinon was the most frequently detected insecticide in surface water in the NAWQA program. It is detected more frequently and at higher concentrations in samples from urban sites than at agricultural sites. Surface waters sampled under the program include rivers, streams, creeks, and runoff from areas with both agricultural and urban pesticide use. Many of the studies conducted have been located in areas where pesticide use and agricultural production are considered to be high. However, the studies have not been targeted explicitly to diazinon use patterns, *per se*. Based on the data presented in the EFED memorandum, diazinon was detected frequently (35% of NAWQA samples) at low concentrations ranging from non-detectable to 3.8 ug/L. The maximum detection reported (3.8 ug/L) was from a stream sampling. The size or relevance of the stream from which the maximum detection was reported to a drinking water source was not given. Degradates of diazinon were not included in the NAWQA analyses.

EFED used the PRZM/EXAMS surface water quality model to provide upper bound estimates on diazinon for comparison to a drinking water level of comparison (DWLOC). Model estimates from a scenario representing diazinon use on walnuts in California was selected for use in the human health risk assessment as it represented a high-end use pattern. A maximum diazinon concentration of 22 ug/L, and a 90th percentile annual average diazinon concentration of 5.8 ug/L were recommended for use in acute and chronic risk assessments, respectively. The details of the modeling efforts and results are detailed in the aforementioned EFED memorandum.

Ambient Surface Water Quality

The data presented below in Tables 15 through 17 are from USGS' NAWQA program. It appears from these data that concentrations of diazinon in ambient surface water increase with decreasing size of the water body sampled, and that urban areas have a greater frequency of detection and higher concentrations for diazinon than agricultural areas. This is supported by diazinon's use pattern, which is largely urban.

Concentrations in large streams and rivers draining relatively large basins sampled under the NAWQA program (1992 - 1996) ranged from non-detectable to 0.40 ug/L, and the 95th percentile concentration value was 0.07 ug/L. The limit of detection was 0.002 ug/L. Samples were collected during a one year period from the first 20 NAWQA study units (period not given). Samples collected during storm events were excluded to avoid bias resulting from repeated sampling during extreme conditions.

Table 15. Results for Diazinon from USGS NAWQA surface water monitoring program for 14 integrator sites on large streams and rivers (ug/L).						
Sites	Samples	Detects*	Range ¹	Mean	95 th Percentile	Median
14	245	111 (45%)	0.4 - ND	NR ²	0.073	NR

¹ Range and 95th percentile values determined from all samples.

² Not reported.

* Percentage of detects/number of samples.

Concentrations in streams in relatively small basins (either agricultural or urban) sampled under the NAWQA program (1992 - 1996) ranged from non-detectable to 1.9 ug/L, and the 95th percentile concentration value was 0.43 ug/L at the urban sites. At the agricultural sites, concentrations ranged from non-detectable to 1.2 ug/L, and the 95th percentile concentration value was 0.027

ug/L The limit of detection was 0.002 ug/L. Samples were collected during a one year period from the first 20 NAWQA study units (period not given). Samples collected during storm events were excluded to avoid bias resulting from repeated sampling during extreme conditions.

Table 16. Results for Diazinon from USGS NAWQA surface water monitoring program for 40 agricultural and 11 urban streams in relatively small basins. (ug/L).							
Land Use	Sites	Samples	Detects*	Range ¹	Mean	95 th Percentile	Median
Urban	11	326	244 (75%)	1.9 - ND	NR ²	0.430	NR
Agricultural	40	1000	169 (17%)	1.2 - ND	NR ²	0.027	NR

¹ Range and 95th percentile values determined from all samples.

² Not reported.

* Percentage of detects/number of samples.

Concentrations in all streams sampled under the NAWQA program (1992 - 1996) ranged from non-detectable to 2.9 ug/L , and the 95th percentile concentration value was 0.24 ug/L at the urban sites. At the agricultural sites, concentrations ranged from non-detectable to 3.8 ug/L , and the 95th percentile concentration value was 0.042 ug/L The limit of detection was 0.002 ug/L. All samples collected between 4/20/92 and 12/16/96 were included in the calculated statistics.

Table 17. Results for Diazinon from USGS NAWQA surface water monitoring program for all streams sampled (ug/L).							
Land Use	Sites	Samples	Detects*	Range ¹	Mean	95 th Percentile	Median
Urban	551	2178	1095 (50%)	2.9 - ND	0.05	0.24	0.003
Agricultural	507	2977	703 (24%)	3.8 - ND	0.017	0.042	ND

¹ Range and 95th percentile values determined from all samples.

² Not reported.

* Percentage of detects/number of samples.

Sampling along major US rivers (the Rio Grande, Mississippi, Columbia, and Colorado) under the USGS NASQAN program (1995 - 1998) show that 95th percentile concentration values for diazinon ranged from 0.055 to 0.003 ppb. Detection limits were 0.002 ug/L for diazinon. No metabolites were included in the analyses.

Several studies conducted in the San Joaquin Valley along the major rivers there (the San Joaquin, Merced, Russian, Tolumne, Salinas, and Sacramento) by either the USGS, California state agencies, or individuals provide data showing low levels of diazinon in these surface waters. Calculated statistics reported for the 95th percentile concentration of diazinon ranged from non-detectable to 1.7 ppb, and mean concentrations ranged from non-detectable to 1.18 ppb. No metabolites were included in the analyses.

Diazinon has been detected in influent and effluent from Publicly Owned Treatment Works (POTWs) indicating that diazinon is entering sewer systems in urban areas as a result of residential uses. Diazinon has also been detected in air, rain, and fog in California. (See EFED memorandum for details).

Surface-Water Sourced Drinking Water

Preliminary results from an industry-sponsored study designed to monitor for diazinon and

diazinon oxon in finished drinking water in community water systems sourced by surface water have been submitted to the Agency for review. These data are under review at this time. HED recommends a reassessment of exposure to diazinon in drinking water, once this survey is completed, submitted, and reviewed.

d. Drinking Water Risk Characterization

EFED provided the following values in Table 8 for use in acute and chronic drinking water risk estimates. The values selected were based on a combination of monitoring and modeling.

Table 18. Estimated diazinon concentrations (ug/L) in drinking water		
Type	Acute	Chronic
Surface Water		
Agricultural Use	2.3 - 22	0.19 - 5.8
Urban Use	3.0 - 22	0.46 - 5.8
Ground Water	0.90	0.90

Concentration Estimates for Acute Risk Assessment

For surface water, under the acute column, a range of values was provided by EFED. The low value represents the 95th percentile concentration out of all reported maximum concentrations for diazinon in surface water from all surface water monitoring studies for agricultural (2.3 ug/L) and urban (3.0 ug/L) uses. Although potential drinking water sources were included in the overall database for surface water, there was no characterization as to what type of water source the selected values in the table above represent, i.e., large river versus small stream, etc. The high value represents the 90th percentile maximum concentration value predicted by the PRZM/EXAMS model for diazinon use in California on walnuts (22 ug/L). For ground water, under the acute column, the single value presented represents the 95th percentile concentration out of all reported maximum concentrations for diazinon from all ground water monitoring studies (0.9 ug/L). There was no characterization as to what type of water resource the value represents, i.e., shallow monitoring well versus drinking water well. The 0.9 ug/L value from monitoring compares favorably with the SCI-GROW (ground water) model estimate of 0.8 ug/L for shallow monitoring wells. The SCI-GROW estimate represents a 99th percentile concentration value for pesticides in shallow groundwater (personal communication with Dr. M. Barrett, EFED).

Concentration Estimates for Chronic Risk Assessment

For surface water, under the chronic column, a range of values was provided. The low value represents the 95th percentile of the arithmetic mean concentrations calculated from all reported sample concentrations (detects and non-detects) for diazinon in surface water from all surface water monitoring studies for agricultural (0.19 ug/L) and urban (0.46 ug/L) uses. The high value represents the 90th percentile of the annual average concentration values predicted by the PRZM/EXAMS model for diazinon use in California on walnuts (5.8 ug/L). For ground water, under the chronic column, the single value presented represents the 95th percentile concentration out of all reported maximum concentrations for diazinon from all ground water monitoring studies (0.9 ug/L) and is the same as the value reported for use in acute assessments. This value compares favorably with the SCI-GROW (ground water) model estimate of 0.8 ug/L. However, HED notes that average (mean) concentration values are more appropriate for chronic risk assessment. Although average values were reported for concentrations of diazinon in groundwater for some studies, the average values were determined from all samples analyzed and not on a per well basis. Average concentration values per well from monitoring data are considered more appropriate for

use chronic risk assessment. In the absence of these average values, HED used the 99th percentile model estimate from SCI-GROW and the 95th percentile concentration from monitoring data provided by EFED for comparison against chronic DWLOCs.

Drinking Water Risk from Acute Exposures

HED calculated acute DWLOCs for several other subpopulations of interest. These values are provided in Table 19 below and compared to monitoring data and model estimates of diazinon in surface and groundwater.

In general,

$$\text{DWLOC}_{\text{acute}} = \frac{(\text{acute water exposure, mg/kg/day})(\text{body weight})}{(\mu\text{g/L})(\text{water consumption, L/day})(10^{-3} \text{ mg}/\mu\text{g})}$$

where acute water exposure = [aPAD (mg/kg/day) - acute food exposure (mg/kg/day)]

The acute PAD is 0.0025 mg/kg/day, and water consumption is 2 L/day for adults and 1 L/day for children; and body weight is 70 kg for total US population, 60 kg for females 13+ years old, and 10 kg for children 1 to 6 years old and infants (non-nursing, <1 year old).

Table 19. Comparison of Acute DWLOC Values to Monitoring and Model Concentration Estimates of Diazinon Concentrations in Surface and Ground Waters					
Population Group	DWLOC (ppb) for Acute Assessment ¹	Groundwater (ppb)		Surface water (ppb)	
		monitoring	model ²	monitoring	model
General U.S.	57/64	0.90	0.80	2.3-3.0	22
Non-Hispanic/non-white/non-black	32/57	0.90	0.80	2.3-3.0	22
Females (13+ years old)	47/54	0.90	0.80	2.3-3.0	22
Children (1-6 years old)	10/13	0.90	0.80	2.3-3.0	22
All Infants, (<1 year old)	18/18	0.90	0.80	2.3-3.0	22
¹ Two DWLOC acute values were calculated; one values based on dietary exposure including sheep commodities, and one value based on dietary exposure excluding sheep commodities, respectively. ² For ground water, the 90-day average concentration from SCI-GROW represents a 99 th percentile concentration in ground water, and is the model concentration estimate used for purposes of comparison against the acute DWLOC values.					

Concentration estimates for acute exposures to diazinon in *groundwater* based on model estimates and monitoring data are less than the acute DWLOC values for all subgroups analyzed. HED concludes there is no drinking water concern for diazinon in groundwater-sourced drinking water. Concentration estimates for acute exposures to diazinon in *surface water* based on ambient water quality *monitoring* data are less than the acute DWLOC values for all subgroups analyzed. However, comparing acute DWLOCs values to *model* estimates for concentrations of diazinon in ambient surface water (which are approximately one order of magnitude greater than the

concentration estimates from monitoring data), there is a potential concern for infants and children (1 to 6 years old). Based on the available information, HED cannot conclude that there is no concern for exposures to diazinon in surface-water-sourced drinking water. However, given the uncertainty in the model and monitoring estimates relative to each other (10x), and therefore, the uncertainty relative to diazinon concentrations in actual drinking water, HED recommends that the acute exposures to diazinon in drinking water be reassessed once surface-water sourced drinking water monitoring data on diazinon become available for use.

Drinking Water Risk from Chronic Exposures

HED calculated chronic DWLOCs for several other subpopulations of interest. These values are provided in Table 20 below and compared to monitoring data and model estimates of diazinon in surface and groundwater.

In general,

$$\text{DWLOC}_{\text{chronic}} = \frac{(\text{chronic water exposure, mg/kg/day})(\text{body weight})}{(\mu\text{g/L}) \quad (\text{water consumption, L/day})(10^{-3} \text{ mg}/\mu\text{g})}$$

where chronic water exposure* = [cPAD (mg/kg/day) - chronic food exposure (mg/kg/day)]

*[Note: There are no homeowner uses that result in chronic, long-term exposures to diazinon in the home.]

The chronic PAD is 0.0002 mg/kg/day, and water consumption is 2 L/day for adults and 1 L/day for children; and body weight is 70 kg for total US population, 60 kg for females 13+ years old, and 10 kg for children 1 to 6 years old and infants (non-nursing, <1 year old).

Table 20. Comparison of Chronic DWLOC Values to Monitoring and Model Concentration Estimates of Diazinon Concentrations in Surface and Ground Waters					
Population Group	DWLOC (ppb) for Chronic Assessment	Groundwater (ppb)		Surface water (ppb)	
		monitoring ²	model ¹	monitoring	model
General U.S.	6.3	0.90	0.80	0.19/0.46	5.8
Non-Hispanic/non-white/non-black	6	0.90	0.80	0.19/0.46	5.8
Females (13+ years old)	5.3	0.90	0.80	0.19/0.46	5.8
Infants	2.0	0.90	0.80	0.19/0.46	5.8
Children (1-6 years old)	2.0	0.90	0.80	0.19/0.46	5.8
¹ For ground water, the 90-day average concentration from SCI-GROW represents the 99 th percentile concentration value in groundwater and is compared to the chronic DWLOC values. ² 95 th percentile values based on all reported maximum concentration values from groundwater monitoring data. Mean concentration values per well were not provided, but are more appropriate for use in chronic risk assessment.					

Concentration estimates for long-term, chronic exposures to diazinon in *groundwater* based on

model estimates and monitoring data are less than the chronic DWLOC values for all subgroups analyzed (Table 20). HED concludes that there is no concern for chronic exposures to diazinon in groundwater-sourced drinking water. Concentration estimates for chronic exposures to diazinon in ambient *surface water* based on *monitoring* data are less than the chronic DWLOC values for all subgroups also indicating no concern for chronic exposures to diazinon in surface water-sourced drinking water. However, comparing chronic DWLOCs values to *model* estimates for concentrations of diazinon in surface water (which are approximately one order of magnitude greater than the concentration estimates from monitoring data) there is a potential concern for infants, children (1 to 6), and females 13+. Therefore, HED cannot conclude that there is no concern for exposures to diazinon in surface-water-sourced drinking water. However, given the uncertainty in the model and monitoring estimates relative to each other (10x), and therefore, the uncertainty relative to diazinon concentrations in drinking water, and the proximity of the model estimates to the DWLOC values, HED recommends reassessing the potential chronic exposure to diazinon in drinking water once surface-water sourced drinking water monitoring data on diazinon become available for use.

4. Exposure Assessment Estimates for Occupational and Non-occupational (Residential) Scenarios and Their Risk Characterization

(a). General Assumptions

HED has conducted a screening-level assessment for occupational and residential (non-occupational) exposure scenarios resulting from diazinon's registered uses. A margin of exposure (MOE) greater than 100 for short-term, intermediate-term, and long-term dermal occupational and residential exposures to diazinon does not exceed HED's level of concern. For occupational and residential inhalation exposures of any duration, a MOE of 300 is necessary. The MOE for residential, non-dietary, oral exposures (for children's hand-to-mouth exposure) is also 100. When MOEs for multiple exposure pathways differ, but exposures across those pathways must be combined under an aggregate risk assessment, HED uses the Aggregate Risk Index method (ARI method). ARIs greater than 1.0, do not exceed HED's level of concern.

HED has determined that there are potential short-, and intermediate-term exposure scenarios for mixer/loaders, applicators, and mixer/loader/applicators during usual use patterns associated with diazinon. Based on the use patterns, 27 major occupational exposure scenarios were identified for handlers, and 4 major exposure scenarios were identified for postapplication exposure (3 for agriculture activities and 1 for greenhouse activities). For homeowners, 7 major residential exposure scenarios for homeowner handlers were identified, and 20 major postapplication exposure scenarios were also identified. Of these 20, 8 are from outdoor applications to turf, and 12 are from indoor applications from crack and crevice treatments administered by professional, certified applicators (PCOs). The turf applications can be made with either liquid or granular formulations.

For all occupational risk assessments, the adult body weight was assumed to be 70 kg. For all residential risk assessments, a 70 kg adult body weight and a 15 kg body weight for 3 year old toddlers were assumed. Dermal and inhalation exposures are assumed to occur for adults under both occupational and residential handler/applicator exposure scenarios. Short-term postapplication dermal and inhalation exposures are assumed to occur for adults under the residential exposure scenario. Short-term postapplication dermal, inadvertent oral (hand-to-mouth), and inhalation exposures are assumed to occur for children under the residential exposure scenario. Postapplication inhalation exposures are normally considered for indoor residential

applications as is the case for crack and crevice treatments with diazinon. Normally, postapplication inhalation exposures are considered insignificant for outside lawn and garden treatments, but in this case, data were submitted on inhalation exposures after lawn treatments with diazinon, and therefore, these data were used to assess inhalation exposures after lawn treatments.

The following toxicological endpoints were used to estimate occupational and residential risks: for short-term dermal exposures, an oral NOAEL of 0.25 mg/kg/day; for intermediate- and long-term dermal exposures, an oral NOAEL of 0.02 mg/kg/day; and for inhalation exposures (all time periods) an inhalation LOAEL of 0.026 mg/kg/day. The assessment assumes 100% absorption through both dermal and inhalation exposure routes. Target margins of exposure (MOEs) for short- and intermediate-term dermal risk assessments are 100 resulting from the following uncertainty factors: a 10x for interspecies variability and 10x for intra-species extrapolation. For inhalation risk assessments (all time periods) the target MOE is 300x resulting from uncertainty factors for interspecies variability (10x), intra-species extrapolation (10x), and for lack of a NOAEL in the critical study and consequent use of a LOAEL (3x).

Data quality is a critical parameter in the interpretation of the results of any exposure assessment. No chemical specific mixer/loader/applicator exposure data were available from the registrant to be used in supporting the reregistration of diazinon. Handler exposure risk assessments were conducted using the surrogate data from the PHED data base (Version 1.1). Data contained in PHED are assigned grades (A through E) based on the overall quality of the analytical recovery data generated concurrently with actual data points (i.e., laboratory recovery, field recovery and stability data). All exposure assessments using PHED were based on the surrogate unit exposure values currently being used as a standard source of exposure values, and the use data presented by the registrant. Values were defined using high quality data and a large number of replicates to calculate exposures if the data were available. However, if not available, rangefinder exposure values were calculated using all data available in PHED.

In general, for PHED data, "Best Available" grades are defined by Exposure Scientific Advisory Council (SAC) SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates per body part

Medium = grades A, B, and C and 15 or more replicates per body part

Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

(b). Occupational Mixer/Loader/Handler/Applicator Exposure and Assumptions

Exposure data requirements are triggered based on the potential for exposure and the toxicological profile of the active ingredient. Exposure analyses for the use/activity patterns associated with diazinon have been completed for each handler (i.e., mixer/loader/applicator) scenario of concern to the Agency and data gaps for specific exposure scenarios have been identified.

Occupational exposures can potentially occur to pesticide handlers, mixers, loaders, and applicators working with diazinon from a multitude of application techniques and multiple formulations (e.g., liquids and solids). Diazinon treatments include, but are not limited to, aerial applications, airblast, groundboom, tractor and push-type granular spreaders, and handheld spray equipment. Occupational exposure to diazinon residues can occur to postapplication workers

during harvesting activities.

Major occupational exposure scenarios (27) are given below:

Occupational Handler scenarios are as follows:

- 1a. Mixing/loading liquids to support aerial/chemigation applications.
Short-, and intermediate-term use patterns.
- 1b. Mixing/loading liquids to support groundboom applications.
Short-, and intermediate-term use patterns.
- 1c. Mixing/loading liquids to support airblast applications.
Short-, and intermediate-term use patterns.
- 1d. Mixing/loading liquids to support rights-of-way-sprayer applications.
Short-, intermediate-, and long- term use patterns.*
- 1e. Mixing/loading liquids to support high-pressure hand-wand (livestock areas) applications.
Short-, intermediate-, and long- term use patterns.*
- 2a. Mixing/loading wettable powders to support aerial/chemigation applications.
Short-, and intermediate-term use patterns.
- 2b. Mixing/loading wettable powders to support groundboom applications.
Short-, and intermediate-term use patterns.
- 2c. Mixing/loading wettable powders to support airblast applications.
Short-, and intermediate-term use patterns.
- 2d. Mixing/loading wettable powders to support rights-of-way-sprayer applications.
Short-, intermediate-, and long- term use patterns.*
- 2e. Mixing/loading wettable powders to support high-pressure handwand (livestock areas) applications. *Short-, intermediate-, and long- term use patterns*.*
3. Loading granules to support tractor-drawn broadcast spreaders applications
Short-, and intermediate-term use patterns.
- 4a. Applying sprays with an airblast. *Short-, and intermediate-term use patterns.*
- 4b. Applying sprays with groundboom. *Short-, and intermediate-term use patterns.*
- 4c. Applying liquid with a paintbrush. *Short-, intermediate-, and long-term use patterns*.*
- 4d. Applying sprays with an airless sprayer. *Short-, and intermediate-term use patterns.*
- 4e. Applying sprays with a high-pressure handwand (livestock areas).
Short-, intermediate-, and long-term use patterns.*
- 4f. Applying sprays with a handgun (lawn).
Short-, intermediate-, and long-term use patterns.*
- 4g. Applying sprays with a rights-of-way sprayer.
Short-, intermediate, and long-term use patterns.*
- 4h. Applying sprays with a fixed-wing aircraft. *Short-, and intermediate-term use patterns.*
5. Applying granules with a tractor drawn spreader.
Short-, and intermediate-term use patterns.
6. Flagging for sprays. *Short-, and intermediate-term use patterns.*
- 7a. Mixing/loading/applying liquids with a low pressure hand-wand.
Short-, intermediate, and long-term use patterns.*
- 7b. Mixing/loading/applying liquids with a backpack sprayer.
Short-, intermediate, and long-term use patterns.*
- 7c. Mixing/loading/applying liquids with a high pressure hand-wand (greenhouse).
Short-, intermediate, and long-term use patterns.*
8. Mixing/loading/applying wettable powders with a low pressure hand-wand.

Short-, intermediate, and long-term use patterns.*

9a. Loading/applying granules with a belly grinder.

Short-, and intermediate-term use patterns.

9b. Loading/applying granules with a push-type spreader.

Short-, and intermediate-term use patterns.

Use scenarios noted with an asterisk (*) have the potential for long-term exposures. Potential risks from any long-term exposures that may occur under these use scenarios are adequately addressed by the intermediate-term exposure assessment because both risk assessments use the same toxicological endpoint (0.02 mg/kg/day). There were no exposure data available for this chemical for seed/seedling treatments and sheep treatments.

Table 21 gives the standard (default) number of acres treated that was used by HED to estimate daily exposure levels in each occupational handler scenario.

Table 21 . Occupational Handler Standard (Default) Daily Area(s) Treated per Scenario for Diazinon		
<i>Exposure Scenario and Equipment / Usage</i>	<i>Value</i>	<i>Units</i>
Mixer/Loader		
<i>Scenario # 1 Mixing/loading liquids</i>		
a) Aerial / Chemigation	350	Acres per day
b) Groundboom	80	Acres per day
c) Airblast	40	Acres per day
d) Rights-of-Way Sprayer	40	Acres per day
e) High-pressure Handwand (Livestock Areas)	1000	Gallons per day
<i>Scenario # 2 Mixing/loading wettable powders</i>		
a) Aerial / Chemigation	350	Acres per day
b) Groundboom	80	Acres per day
c) Airblast	40	Acres per day
d) Rights-of-Way Sprayer	40	Acres per day
e) High-pressure Handwand (Livestock Areas)	1000	Gallons per day
<i>Scenario # 3 Loading granules</i>		
Tractor-drawn broadcast spreaders	80	Acres per day
Applicators		
<i>Scenario # 4 Applying sprays</i>		
a) Airblast	40	Acres per day
b) Groundboom	80	Acres per day
c) Paintbrush	5	Gallons per day
d) Airless Sprayer	40	Gallons per day
e) High-pressure Handwand (Livestock Areas)	1000	Gallons per day
f) Handgun (lawn) Sprayer	3	Acres per day
g) Rights-of-Way Sprayer	40	Acres per day
h) Fixed-wing Aircraft	350	Acres per day
<i>Scenario # 5 Applying granules</i>		
Tractor-drawn broadcast spreaders	80	Acres per day
<i>Scenario # 6 Flagging (In support of aerial application)</i>		
Sprays	350	Acres per day
Mixer/Loader/Applicator		
<i>Scenario # 7 Mixing/loading/applying liquids</i>		
a) Low Pressure Handwand	1	Acres per day
b) Backpack sprayer	1	Acres per day
c) High pressure handwand (greenhouse)	1000	Gallons per day
<i>Scenario # 8 Mixing/loading/applying wettable powders</i>		
Low pressure handwand	1	Acres per day
<i>Scenario # 9 Loading/applying granules</i>		
a) Belly Grinder	1	Acres per day
b) Push-type spreader	3	Acres per day

Potential daily exposure is calculated using the following formula:

$$\text{Daily Exp. (mg ai/day)} = \text{Unit Exp. (mg ai/lb ai)} \times \text{Max. Appl. Rate (lb ai/acre)} \\ \times \text{Max. Area Treated (acres/day)}$$

These calculations of daily exposure to diazinon by handlers and homeowners are used to calculate the daily dose to those handlers and homeowners.

The daily dose is calculated using the following formula:

$$\text{Daily Dose (mg ai/kg/day)} = \text{Daily Exp. (mg ai/day)} / \text{body weight (kg)}$$

These calculations of daily dose of diazinon received by handlers and homeowners are used to assess the dermal risk to those handlers and homeowners. The short-term and intermediate-term MOEs were calculated using the following formula:

$$\text{MOE} = \text{NOAEL (mg/kg/day)} / \text{Daily Dose (mg/kg/day)}$$

Tables 22 (a-c) provide estimates of daily unit dermal and inhalation exposures for three levels of protective equipment for the major exposure and use scenarios. Table 22(a) provides dermal and inhalation exposure estimates for baseline protection, which includes a single layer of clothing including long pants, a long-sleeved shirt, and no gloves. Table 22(b) provides dermal and inhalation exposure estimates for additional personal protective equipment (PPE), which includes wearing coveralls over a single layer of clothing and chemical-resistant gloves. Table 22(c) provides dermal and inhalation exposure estimates through the use of engineering controls, which refers to the use of a single layer of clothing and closed mixing systems and closed-cab tractors. The tables also provide the PHED parameters and caveats specific to each exposure scenario. Comments at the bottom of each table include any other critical descriptions of the data including information pertaining to the quality of the exposure data, level of confidence, and any protection factors applied to the exposure data.

Table 22a. Diazinon Baseline Occupational PHED Unit Exposures ^a											
Exposure Scenario Equipment / Usage	Dermal Unit Exposure (mg/lb ai (dermal+hands)	Dermal Data Confid.	Dermal Grades	Dermal Repli.	Hand Grade	Hand Repli.	Clothing Scenario ^b	Inhalation Unit Exposure (ug/lb ai)	Inhalation Data Confid.	Inhalation Grades	Inhalation Repli.
Mixer/Loader											
<i>Scenario # 1 Mixing/loading liquids</i>											
a) Aerial / Chemigation b) Groundboom c) Airblast d) Rights-of-Way Sprayer e) High-pressure Handwand (Livestock Areas)	2.9	High	AB	72-122	AB	53	LSS, LP, NG	1.2	High	AB	85
<i>Scenario # 2 Mixing/loading wettable powders</i>											
a) Aerial / Chemigation b) Groundboom c) Airblast d) Rights-of-Way Sprayer e) High-pressure Hand-wand (Livestock Areas)	3.7	Low	ABC	22- 45	ABC	7	LSS, LP, NG	43	Medium	ABC	44
<i>Scenario # 3 Loading granules</i>											
Tractor-drawn broadcast spreaders	0.0084	Low	ABC	33-78	All	10	LSS, LP, NG	1.7	High	AB	58
Applicator											
<i>Scenario # 4 Applying sprays / liquids</i>											
a) Airblast	0.36	High	AB	32-49	AB	22	LSS,LP,NG	4.5	High	AB	47
b) Groundboom	0.014	High	AB	23-42	AB	29	LSS,LP,NG	0.74	High	AB	22
c) Paintbrush	180	Low	C	14-15	B	15	LSS,LP,NG	280	Medium	C	15
d) Airless Sprayer	38	High	B	15	B	15	LSS,LP,NG	830	Medium	C	15
e) High-pressure Hand-wand (Livestock.Areas.)	1.8	Low	All	9-11	All	2	LSS,LP,NG	79	Low	All	11
f) Handgun (lawn) Sprayer	0.77	Low	C	0-14	C	14	LSS,LP,NG	1.4	Low-M	AB	14
g) Rights-of-Way Sprayer	1.3	Low	ABC	4-30	AB	16	LSS,LP,NG	3.9	High	A	16
h) Fixed-wing Aircraft	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
<i>Scenario # 5 Applying granules</i>											
Tractor-drawn broadcast spreaders	0.0099	Low	AB	1-5	AB	5	LSS,LP,NG	1.2	Low	AB	5
<i>Scenario # 6 Flagging (In support of aerial application)</i>											
Sprays	0.011	High	AB	18-28	AB	30	LSS,LP,NG	0.35	High	AB	28
Mixer/Loader/Applicator											
<i>Scenario # 7 Mixing/loading/applying liquids</i>											
a) Low Pressure Hand-wand	100	Low	ABC	9-80	All	70	LSS,LP,NG	30	Medium	ABC	80
b) Backpack sprayer	2.5	Low	AB	9-11	C	11	LSS,LP,NG	30	Low	A	11

Table 22a. Diazinon Baseline Occupational PHED Unit Exposures ^a											
Exposure Scenario Equipment / Usage	Dermal Unit Exposure (mg/lb ai) (dermal+hands)	Dermal Data Confid.	Dermal Grades	Dermal Repli.	Hand Grade	Hand Repli.	Clothing Scenario ^b	Inhalation Unit Exposure (ug/lb ai)	Inhalation Data Confid.	Inhalation Grades	Inhalation Repli.
c) High pressure hand-wand (greenhouse)	3.5	Low	AB	7-13	C	13	LSS,LP,NG	120	Low	A	13
<i>Scenario # 8 Mixing/loading/applying wettable powders</i>											
Low pressure hand-wand	8.6	Medium	ABC	16	AB	15	LSS,LP,NG	1100	Medium	ABC	16
<i>Scenario # 9 Loading/applying granules</i>											
a) Belly Grinder	10	Medium	ABC	29-45	ABC	23	LSS,LP,NG	62	High	AB	40
b) Push-type spreader (no head & neck data available)	2.9	Low	C	0-15	C	15	LSS,LP,NG	6.3	High	B	15

^a The Pesticide Handler Exposure Database (PHED) Version 1.1

^b Baseline Dermal Unit Exposure is based on workers wearing long sleeve shirts and long pants, and no gloves (LSS, LP, NG); open mixing/loading; and open cab tractor; except for backpack sprayers. Chemical resistant gloves are included for the backpack assessment because the no glove scenario is not available. Baseline data are not available for aerial application. Baseline inhalation exposure represents no respirator.

NF = Not Feasible; **ND** = No Data.

Table 22b. Diazinon Maximum PPE PHED Unit Exposures ^a											
Exposure Scenario Equipment / Usage	Dermal Unit Exposure (mg/lb ai) (dermal+hands)	Dermal Data Confid.	Dermal Grades	Derm. Repli.	Hand Grade	Hand Repli.	Clothing Scenario ^b	Inhalatn. Unit Exposure (ug/lb ai)	Inhalatn. Data Confid.	Inhalatn. Grades	Inhalatn. Repli.
Mixer/Loader											
<i>Scenario # 1 Mixing/loading liquids</i>											
a) Aerial / Chemigation b) Groundboom c) Airblast d) Rights-of-Way Sprayer e) High-pressure Hand-wand (Livestk. Areas)	0.017	High	AB	72- 122	AB	59	DLC, CRG	0.24	High	AB	85
<i>Scenario # 2 Mixing/loading wettable powders</i>											
a) Aerial / Chemigation b) Groundboom c) Airblast d) Rights-of-Way Sprayer e) High-pressure Handwand (Livestk Areas)	0.13	Medium	ABC	22- 45	ABC	24	DLC, CRG	8.6	Medium	ABC	44
<i>Scenario # 3 Loading granules</i>											
Tractor-drawn broadcast spreaders	0.0034	Low	ABC	12-59	AB	45	DLC, CRG	0.34	High	AB	58
Applicator											

Table 22b. Diazinon Maximum PPE PHED Unit Exposures ^a											
Exposure Scenario Equipment / Usage	Dermal Unit Exposure (mg/lb ai) (dermal+hands)	Dermal Data Confid.	Dermal Grades	Derm. Repli.	Hand Grade	Hand Repli.	Clothing Scenario ^b	Inhalatn. Unit Exposure (ug/lb ai)	Inhalatn. Data Confid.	Inhalatn. Grades	Inhalatn. Repli.
Scenario # 4 Applying sprays / liquids											
a) Airblast	0.22	High	AB	31-48	AB	18	DLC, CRG	0.9	High	AB	47
b) Groundboom	0.011	Medium	AB	23-42	ABC	21	DLC, CRG	0.15	High	AB	22
c) Paintbrush	22	Low	C	14-15	AB	15	DLC, CRG	56	Medium	C	15
d) Airless Sprayer	14	High	B	15	B	15	DLC, CRG	170	Medium	C	15
e) High-pressure Hand-wand (Livestk Areas)	0.36	Low	All	9-11	All	9	DLC, CRG, R	16	Low	All	11
f) Handgun (lawn) Sprayer	0.19	Low	C	0-14	C	14	DLC, CRG, R	0.28	Low-M	AB	14
g) Rights-of-Way Sprayer	0.29	Low	ABC	4-20	AB	4	DLC, CRG, R	0.78	High	A	16
h) Fixed-wing Aircraft	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Scenario # 5 Applying granules											
Tractor-drawn broadcast spreaders	0.0042	Low	AB	1-5	AB	5	DLC, CRG, R	0.24	Low	AB	5
Scenario # 6 Flagging (In support of aerial application)											
Sprays	0.01	High	AB	18-28	AB	30	DLC, CRG, R	0.07	High	AB	28
Mixer/Loader/Applicator											
Scenario # 7 Mixing/loading/applying liquids											
a) Low Pressure Handwand	0.37	Low	ABC	9-80	ABC	10	DLC, CRG, R	6	Medium	ABC	80
b) Backpack sprayer	1.6	Low	AB	9-11	C	11	DLC, CRG, R	6	Low	A	11
c) High pressure handwand (greenhouse)	1.6	Low	AB	7-13	C	13	DLC, CRG, R	24	Low	A	13
Scenario # 8 Mixing/loading/applying wettable powders											
Low pressure handwand	6.2	Medium	ABC	16	AB	15	DLC, CRG, R	220	Medium	ABC	16
Scenario # 9 Loading/applying granules											
a) Belly Grinder	5.7	Low	ABC	29-45	All	20	DLC, CRG, R	12	High	AB	40
b) Push-type spreader (no head & neck data available)	0.73	Low	C	0-15	C	15	DLC, CRG, R	1.3	High	B	15

^a The Pesticide Handler Exposure Database (PHED) Version 1.1

^b Additional Personal Protective Equipment (PPE) to reduce dermal exposures = workers wear coveralls over single layer clothing and chemical resistant gloves [Double Layer Clothing with Chemical Resistant Gloves (DLC, CRG)]. PPE data are not available for aerial application. PPE inhalation unit exposure represents use of a respirator (R) = dust/mist respirator applied to the baseline unit exposure (Decreases the baseline unit exposure by 80%, if and only if, the worker has achieved a protective seal. This is accomplished by the worker being medically qualified to wear the specific respirator, fit tested to ensure a protective seal was achieved, and he/she has had the appropriate training to maintain the respirator in good condition in accordance with the American National Standards Institute (ANSI) and or OSHA 29CFR 1910.34).

NF = Not Feasible; ND = No Data

Table 22c . Diazinon Engineering Controls PHED Unit Exposures ^a											
Exposure Scenario Equipment / Usage	Dermal Unit Exposure (mg/lb ai) (dermal+hands)	Derm. Data Confid.	Derm. Grades	Derm. Repli.	Hand Grade	Hand Repli.	Clothing Scenario ^b	Inhalatn. Unit Exposure (ug/lb ai)	Inhalatn. Data Confid.	Inhalatn. Grades	Inhalatn. Repli.
Mixer/Loader											
<i>Scenario # 1 Mixing/loading liquids</i>											
a) Aerial / Chemigation b) Groundboom c) Airblast d) Rights-of-Way Sprayer e) High-pressure Handwand (Livestk Areas)	0.0086	High	AB	16- 22	AB	31	LSS, LP, CRG	0.083	High	AB	27
<i>Scenario 2 Mixing/loading wettable powders</i>											
a) Aerial / Chemigation b) Groundboom c) Airblast d) Rights-of-Way Sprayer e) High-pressure Handwand (Livestk Areas)	0.021	Low	AB	6- 15	AB	5	LSS, LP, NG	0.24	Low	All	15
<i>Scenario # 3 Loading granules</i>											
Tractor-drawn broadcast spreaders	0.00017	Low	ABC	33- 78	All	10	LSS, LP, NG	0.034	High	AB	58
Applicator											
<i>Scenario # 4 Applying sprays / liquids</i>											
a) Airblast	0.019	High	AB	20-30	AB	20	LSS, LP, CRG	0.45	Low	ABC	9
b) Groundboom	0.005	Medium	ABC	20-31	ABC	16	LSS,LP,NG	0.043	High	AB	16
c) Paintbrush	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
d) Airless Sprayer	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
e) High-pressure Handwand (Livestk Areas)	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
f) Handgun (lawn) Sprayer	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
g) Rights-of-Way Sprayer	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
h) Fixed-wing Aircraft	0.005	Medm	ABC	24-48	AB	34	LSS, LP, NG	0.068	Medm	ABC	23
<i>Scenario # 5 Applying granules</i>											
Tractor-drawn broadcast spreaders	0.0021	High	AB	27-30	AB	24	LSS,LP,NG	0.22	High	AB	37

Table 22c . Diazinon Engineering Controls PHED Unit Exposures ^a											
Exposure Scenario Equipment / Usage	Dermal Unit Exposure (mg/lb ai) (dermal+hands)	Derm. Data Confid.	Derm. Grades	Derm. Repli.	Hand Grade	Hand Repli.	Clothing Scenario ^b	Inhalatn. Unit Exposure (ug/lb ai)	Inhalatn. Data Confid.	Inhalatn. Grades	Inhalatn. Repli.
<i>Scenario # 6 Flagging (In support of aerial application)</i>											
Sprays	0.00022	High	AB	18-28	AB	30	LSS,LP,NG	0.007	High	AB	28
Mixer/Loader/Applicator											
<i>Scenario # 7 Mixing/loading/applying liquids</i>											
a) Low Pressure Handwand	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
b) Backpack sprayer	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
c) High pressure handwand (greenhouse)	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
<i>Scenario # 8 Mixing/loading/applying wettable powders</i>											
Low pressure handwand	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
<i>Scenario # 9 Loading/applying granules</i>											
a) Belly Grinder	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF
b) Push-type spreader	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF

^a The Pesticide Handler Exposure Database (PHED) Version 1.1

^b Engineering Controls = single layer clothing and no gloves - LSS, LP, NG (except where noted chemical resistant gloves -- because the no glove scenario is not available) and closed mixing systems and enclosed cab tractors. Engineering Control inhalation unit exposures represents no respirator usage.

NF = Not Feasible; **ND** = No Data

(c). Occupational Postapplication Exposure

EPA has determined that there are potential short-term and intermediate-term postapplication dermal exposures following typical use patterns associated with diazinon in occupational (non-residential) settings. Neither long-term dermal exposures nor inhalation exposures to diazinon are anticipated for postapplication workers. The reentry interval (REI) is the time required between the last application of diazinon and reentry into the treated field to begin harvesting activities. Therefore, acceptable REIs are determined from an exposure assessment at the point in time when MOEs are equal to or greater than 100.

The REI on current diazinon labels (e.g., EPA Reg. No. 100-460) is 24 hours for fruit and nut crops, vegetable crops, and field crops, and 12 hours for ornamentals.

Dislodgeable foliar residue data are used to estimate postapplication dermal exposures. For diazinon, sufficient dislodgeable foliar residue (DFR) data are available for two crops: oranges (as reported in MRID No. 404666-01) and cabbages (as reported in MRID No. 402029-02). DFR data are insufficient for all other crops that are treated with diazinon. Orange tree data were used to estimate DFR values for other tree crops and grapes. The limit of detection (LOD) for the orange study was $<0.004 \mu\text{g}/\text{cm}^2$. The application rate used in the orange study was 1 lb ai/acre, and the data were extrapolated (linearly) to the maximum labeled rate for tree crops of 3 lb ai/acre. Triplicate orange leaf punch samples were collected at 0, 1, 2, 5, 7, and 14 days after treatment (DAT). The predicted DFR values indicated a dissipation rate of 24 percent diazinon per day for oranges. To estimate DFR values for grapes, DFR values from the

orange study once extrapolated to the maximum use rate for tree crops (3 lb ai/acre) were adjusted (divided by 3) to represent the maximum application rate on grapes of 1 lb ai/acre. The limit of detection (LOD) for the cabbage study was $<0.002 \mu\text{g}/\text{cm}^2$. DFR values from the cabbage study were used to estimate exposure for low-growing crops (i.e., lettuce, broccoli). These crops are considered to have low potential exposure.

(d). Occupational Risk Characterization: Handler/Mixer/Loader/Applicator

(i). Individual Exposure Scenarios

HED has estimated risks for the 27 occupational handler exposure scenarios previously listed. The risk estimates calculated as MOEs are presented in a series of tables. Risk estimates for short-term, dermal exposures are provided in Tables 23(a) and 23(b). Risk estimates for intermediate-term and long-term, dermal exposures are provided in Tables 24(a) and 24(b). Risk estimates for inhalation exposures (any time period) are provided in Tables 25(a) and 25(b). Dermal and inhalation risk estimates were calculated based on the dermal and inhalation unit exposures given in Tables 22 (a-c) for each of the 27 exposure scenarios, the general assumptions about acres treated and body weights given above in Table 21, and on the premise of increasingly protective measures, i.e., starting at baseline protective clothing and moving to additional personal protective equipment (PPE), and finally to the use of engineering controls.

A range of application rates were used in the exposure assessments to provide a range of exposure and risk estimates across various occupational uses of diazinon. Specifically, the exposure and risk estimates presented in Tables 23(a), 24(a), and 25(a) under the headings "minimum", "typical", and "maximum" are based on an application rate of 0.01, 0.02, and 0.08 lbs ai/gallon, respectively. These application rates are believed to represent the low end of the range of application rates for diazinon products with residential uses, and correspond to labeled rates for wettable powder formulations used on beans, beets and broccoli, i.e., crops with a low exposure potential. Note that the lower application rates do not apply to many of the occupational exposure scenarios. Occupational exposure scenarios for which the lower application rates are applicable have been included in Tables 23(a), 24(a), and 25(a). In Tables 23(b), 24(b), and 25(b) the exposure and risk estimates presented under the headings "minimum", "typical", and "maximum" are based on an application rate of 0.20, 2.0, and 5.0 lbs ai/gallon (or 0.25, 1.0, and 4.0 lbs ai/acre), respectively. These application rates are believed to represent the higher range of application rates for diazinon products with agricultural and residential uses, and correspond to labeled rates for formulations used in/on greenhouses, livestock areas, rights-of-way, and non-occupational indoor/outdoor environments with a high exposure potential.

Discussion of Tables 23(a) and 23(b)

Risks Based on Short-Term Dermal Exposure:

- The estimates of risk based on short-term dermal exposure in the tables below indicate that the MOEs are equal to, or greater than 100 using baseline protection for short-term risk for 1 scenario: Scenario (3), Loading granules, tractor-drawn broadcast spreaders at a 0.25 lbs ai/Acre application rate.
- With Additional PPE, MOEs are equal to, or greater than 100 for short-term risk based on dermal exposures for the following 7 scenarios:

- (1c) Mixing/loading liquids for airblast application at a 0.25 lbs ai/Acre application rate;
- (1d) Mixing/loading liquids for right-of-way application at a 0.25 lbs ai/Acre application rate;
- (1e) Mixing/loading liquids with a high-pressure hand-wand in livestock areas at a 0.01 lbs ai/gallon application rate;
- (3) Loading granules, tractor-drawn broadcast spreaders at a 0.25 lbs ai/Acre application rate;
- (4f) Applying sprays, with hand-gun (lawn) sprayers at a 0.25 lbs ai/Acre application rate;
- (5) Applying granules with tractor-drawn broadcast spreaders at a 0.25 lbs ai/Acre application rate;
- (7a) Mixing/Loading/Applying liquids with low pressure hand-wands at a 0.25 lbs ai/Acre application rate;

Using Engineering Controls, MOEs for the following 8 scenarios are equal to, or greater than 100:

- (1b) Mixing/loading liquids for groundboom application at a 0.25 lbs ai/Acre application rate;
- (1c) Mixing/loading liquids for airblast application at a 0.25 lbs ai/Acre application rate;
- (1d) Mixing/loading liquids for right-of-way application at a 0.25 lbs ai/Acre application rate;
- (1e) Mixing/loading liquids for high-pressure handwand application in livestock areas at 0.01 and 0.02 lbs ai/gallon application rates;
- (3) Loading granules for tractor-drawn broadcast application at 0.25, 1.0, and 4.0 lbs ai/Acre application rates;
- (4b) Applying sprays and liquids for groundboom application at a 0.25 lbs ai/Acre application rate;
- (5) Applying granules with a tractor-drawn broadcast spreader at a 0.25 lbs ai/Acre application rate;
- (6) Flagging sprays at 0.25 and 1.0 lbs ai/Acre application rates.

For the following scenarios, MOEs are less than 100, after applying engineering controls (if feasible) and considering the minimum application rate:

- (1a) Mixing/loading liquid for aerial/chemigation applications;
- (2) Mixing/loading wettable powders- all scenarios;
- (4a) Applying sprays/liquid- all scenarios, except for groundboom applications;
- (7) M/L/A liquids with (b) backpacks and (c) low pressure hand-wands;
- (8) M/L/A wettable powders with low pressure hand-wands; and
- (9) L/A granules with (a) belly grinders and (b) push-type spreaders.

Table 23a. Occupational Handler Dermal Short-Term MOEs for 0.01 - 0.08 lbs ai/gallon. (Based on NOAEL = 0.25 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline			Maximum PPE			Engineering Controls		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
Scenario #1 - Mixing/loading liquids									
a) Aerial / Chemigation	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									
c) Airblast									
d) Rights-of-Way Sprayer									
e) High-pressure Handwand (Livestock Areas)	0.60	0.30	0.075	100	52	13	200	100	25
Scenario #2 - Mixing/loading wettable powders									
a) Aerial / Chemigation	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									
c) Airblast									
d) Rights-of-Way Sprayer									
e) High-pressure Handwand (Livestock Areas)	0.47	0.24	0.059	14	6.7	1.7	83	42	10
Scenario #3 - Loading granules									
Tractor-drawn broadcast spreaders	Lower application rates are not applicable to these exposure scenarios.								
Scenarios #4 - Applying sprays / liquids									
a) Airblast	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									
c) Paintbrush	1.9	0.97	0.24	16	8.0	2.0	NF	NF	NF
d) Airless Sprayer	1.2	0.58	0.14	3.1	1.6	0.39	NF	NF	NF
e) High-pressure Handwand (Livestock Areas)	0.97	0.49	0.12	4.9	2.4	0.61	NF	NF	NF
f) Handgun (lawn) Sprayer	Lower application rates are not applicable to these exposure scenarios.								
g) Rights-of-Way Sprayer									
h) Fixed-wing Aircraft									
Scenario #5 Applying granules									
Tractor-drawn broadcast spreaders	Lower application rates are not applicable to these exposure scenarios.								
Scenario #6 - Flagging									
Sprays	Lower application rates are not applicable to these exposure scenarios.								
Scenario #7 Mixing/loading/applying liquids									
a) Low Pressure Handwand	Lower application rates are not applicable to these exposure scenarios.								
b) Backpack sprayer									
c) High pressure handwand (greenhouse)	0.50	0.25	0.062	1.1	0.55	0.14	NF	NF	NF
Scenario #8 Mixing/loading/applying (wetable powders)									

Table 23a. Occupational Handler Dermal Short-Term MOEs for 0.01 - 0.08 lbs ai/gallon. (Based on NOAEL = 0.25 mg/kg/day.)			
Exposure Scenario Equipment /Usage	Baseline	Maximum PPE	Engineering Controls
Low pressure handwand	Lower application rates are not applicable to these exposure scenarios.		
Scenario #9 Loading/applying granules			
a) Belly Grinder	Lower application rates are not applicable to these exposure scenarios.		
b) Push-type spreader (No head &neck data available)			

- ^a Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractor; except for backpack sprayers. Chemical resistant gloves are included for the backpack assessment because the no glove scenario is not available. Baseline data are not available for aerial application.
- ^b Additional Personal Protective Equipment (PPE) to reduce dermal exposures = workers wearing coveralls over single layer clothing and chemical resistant gloves [Double Layer Clothing with Chemical Resistant Gloves (DLC, CRG)]. PPE data are not available for aerial application.
- ^c Engineering Controls = single layer clothing and no gloves (except where noted chemical resistant gloves -- because the no glove scenario is not available) and closed mixing systems and enclosed cab tractors.
- ^d Application rates are a range of representative and maximum rates values found in the diazinon labels. The following labels were used to determine the rates:
 (1) Wettable powders - EPA Reg. No. 100-460 (Diazinon 50 W). Min. rate represents beans, beets, broccoli, etc. Max. rate represents beans, beets, broccoli, etc.
 (2) Liquid formulations - EPA Reg. Nos. 100-784 (AG600 WBC) and 100-461 (AG500 emulsifiable solution). Min. rate represents apricots, beets, etc. Max. rate represents beans, etc. Rights-of-way rate is located on the EPA Reg. No. 100-461.
 (3) Granular - EPA Reg. No. 100-469 (Diazinon 14G) and Diazinon Granular Lawn Insect Control (2 percent).
 Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern. The granular lawn area is restricted to a maximum of 15,000 ft² (EPA Reg. No. 100-468).

Application Rates

	<u>Minimum</u>	<u>Typical</u>	<u>Maximum</u>
Lb. ai./Gallon	0.01	0.02	0.08

Dermal Absorption Correction factor =100%; **NF** = Not Feasible; **ND** = No Data;

Table 23b. Occupational Handler Dermal Short-term MOEs for 0.2 - 5 lbs ai/gallon. or Acre (Based on NOAEL = 0.25 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline			Maximum PPE			Engineering Controls		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
Scenario #1 - Mixing/loading liquids									
<i>a) Aerial / Chemigation</i>	0.069	0.017	0.0043	12	3	0.74	23	5.8	1.4
<i>b) Groundboom</i>	0.30	0.075	0.019	52	13	3.2	100	25	6.4
<i>c) Airblast</i>	0.60	0.15	0.038	100	26	6.4	200	51	13
<i>d) Rights-of-Way Sprayer</i>	0.60	0.15	0.038	100	26	6.4	200	51	13
<i>e) High-pressure Handwand (Livestock Areas)</i>	0.03	0.0030	0.0012	5.2	0.51	0.21	10	1	0.47
Scenario #2 - Mixing/loading wettable powders									
<i>a) Aerial / Chemigation</i>	0.054	0.014	0.0034	1.54	0.38	0.092	9.5	2.4	0.60
<i>b) Groundboom</i>	0.24	0.059	0.015	6.73	1.68	0.42	42	10	2.6
<i>c) Airblast</i>	0.47	0.12	0.03	14	3.4	0.84	83	21	5.2
<i>d) Rights-of-Way Sprayer</i>	0.47	0.12	0.03	14	3.4	0.84	83	21	5.2
<i>e) High-pressure Handwand (Livestock Areas)</i>	0.024	0.0024	0.00095	0.67	0.067	0.027	4.2	0.42	0.17
Scenario #3 - Loading granules									
<i>Tractor-drawn broadcast spreaders</i>	100	26	6.5	260	64	16	5200	1300	320
Scenarios #4 - Applying sprays / liquids									
<i>a) Airblast</i>	4.9	1.2	0.30	8	2.0	0.50	92	23	5.8
<i>b) Groundboom</i>	62	16	3.9	62	16	3.9	180	44	11
<i>c) Paintbrush</i>	0.097	0.0097	0.0039	0.80	0.08	0.032	NF	NF	NF
<i>d) Airless Sprayer</i>	0.058	0.0058	0.0023	0.16	0.016	0.0062	NF	NF	NF
<i>e) High-pressure Handwand (Livestock Areas)</i>	0.049	0.0049	0.0019	0.24	0.024	0.0097	NF	NF	NF
<i>f) Handgun (lawn) Sprayer</i>	30	7.6	1.9	120	31	7.8	NF	NF	NF
<i>g) Rights-of-Way Sprayer</i>	1.4	0.34	0.084	6	1.5	0.38	NF	NF	NF
<i>h) Fixed-wing Aircraft</i>	ND	ND	ND	ND	ND	ND	40	10	2.5
Scenario #5 Applying granules									
<i>Tractor-drawn broadcast spreaders</i>	88	22	5.5	210	52	13	420	100	26
Scenario #6 - Flagging									
<i>Sprays</i>	18	4.6	1.1	20	5	1.2	910	230	57
Scenario #7 Mixing/loading/applying liquids									
<i>a) Low Pressure Handwand</i>	0.69	0.18	0.044	190	47	12	NF	NF	NF
<i>b) Backpack sprayer</i>	28	6.9	1.8	44	11	2.7	NF	NF	NF
<i>c) High pressure handwand (greenhouse)</i>	0.025	0.0025	0.001	0.057	0.0057	0.0022	NF	NF	NF
Scenario #8 Mixing/loading/applying (wetable powders)									

Table 23b. Occupational Handler Dermal Short-term MOEs for 0.2 - 5 lbs ai/gallon. or Acre (Based on NOAEL = 0.25 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline			Maximum PPE			Engineering Controls		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
Low pressure handwand	8.1	2.1	0.51	11	2.8	0.71	NF	NF	NF
Scenario #9 Loading/applying granules									
a) Belly Grinder	6.9	1.8	0.44	12	3.1	0.78	NF	NF	NF
b) Push-type spreader (no head & neck data available)	8.1	2.1	0.50	32	8.1	2.1	NF	NF	NF

^a Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractor; except for backpack sprayers. Chemical resistant gloves are included for the backpack assessment because the no glove scenario is not available. Baseline data are not available for aerial application.

^b Additional Personal Protective Equipment (PPE) to reduce dermal exposures = workers wearing coveralls over single layer clothing and chemical resistant gloves [Double Layer Clothing with Chemical Resistant Gloves (DLC, CRG)]. PPE data are not available for aerial application.

^c Engineering Controls = single layer clothing and no gloves (except where noted chemical resistant gloves -- because the no glove scenario is not available) and closed mixing systems and enclosed cab tractors.

^d Application rates are a range of representative and maximum rates values found in the diazinon labels. The following labels were used to determine the rates:

(1) Wettable powders - EPA Reg. No. 100-460 (Diazinon 50 W). Min. rate represents beans, beets, broccoli, etc. Max. rate represents beans, beets, broccoli, etc.

(2) Liquid formulations - EPA Reg. Nos. 100-784 (AG600 WBC) and 100-461 (AG500 emulsifiable solution). Min. rate represents apricots, beets, etc. Max. rate represents beans, etc. Rights-of-way rate is located on the EPA Reg. No. 100-461.

(3) Granular - EPA Reg. No. 100-469 (Diazinon 14G) and Diazinon Granular Lawn Insect Control (2 percent).

Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern. The granular lawn area is restricted to a maximum of 15,000 ft² (EPA Reg. No. 100-468). Dermal Absorption Correction factor = 100% NA = not applicable; NF = Not Feasible; ND = No Data

Application Rates

	Minimum	Typical	Maximum
Lb. a. i./Acre	0.25	1	4
Lb. a. i./Gallon	0.20	2	5

The results of the intermediate- and long-term dermal handler exposure and risk assessments, (Tables 24(a) and 24(b)) show that except for one scenario, (3) loading granules for a tractor-drawn spreader, all exposure scenarios have MOEs less than 100, and exceed HED's

level of concern, even with engineering controls applied where appropriate.

Discussion of Tables 24(a) and 24(b)

Risks Based on Intermediate- and Long-Term Dermal Exposures:

NO intermediate- or long-term, dermal exposure scenarios using baseline protection have MOEs equal to or greater than 100.

With Additional PPE, MOEs are equal to, or greater than 100 for NO intermediate- or long-term, dermal exposure scenarios.

Using Engineering Controls, MOEs are equal to, or greater than 100 for one intermediate- or long-term, dermal exposure scenario:

(3) Loading granules with a tractor-drawn broadcast spreader at 0.25 and 1.0 lbs ai/acre application rates.

Table 24a. Occupational Handler Dermal Intermediate-term and Long-term MOEs for 0.01 - 0.08 lbs ai/gallon. * (Based on NOAEL = 0.02 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline ^{ad}			Maximum PPE ^{bd}			Engineering Controls ^{cd}		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
Scenario #1 - Mixing/loading liquids									
a) Aerial / Chemigation	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									
c) Airblast									
d) Rights-of-Way Sprayer									
e) High-pressure Handwand (Livestock Areas)	0.048	0.024	6.03E-03	8.2	4.1	1.0	16	8.1	2.0
Scenario #2 - Mixing/loading wettable powders									
a) Aerial / Chemigation	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									
c) Airblast									
d) Rights-of-Way Sprayer									
e) High-pressure Handwand (Livestock Areas)	0.038	0.019	4.73E-03	1.1	0.54	0.14	6.7	3.3	0.83
Scenario #3 - Loading granules									
Tractor-drawn broadcast spreaders	Lower application rates are not applicable to these exposure scenarios.								
Scenarios #4 - Applying sprays / liquids									
a) Airblast	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									

Table 24a. Occupational Handler Dermal Intermediate-term and Long-term MOEs for 0.01 - 0.08 lbs ai/gallon. * (Based on NOAEL = 0.02 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline ^{ad}			Maximum PPE ^{bd}			Engineering Controls ^{cd}		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
c) Paintbrush	0.16	0.078	0.019	1.3	0.64	0.16	NF	NF	NF
d) Airless Sprayer	0.092	9.21E-04	0.012	0.25	0.12	0.031	NF	NF	NF
e) High-pressure Handwand (Livestock Areas)	0.078	0.039	9.72E-03	0.39	0.19	0.049	NF	NF	NF
f) Handgun (lawn) Sprayer	Lower application rates are not applicable to these exposure scenarios.								
g) Rights-of-Way Sprayer									
h) Fixed-wing Aircraft									
Scenarios #5 Applying granules									
Tractor-drawn broadcast spreaders	Lower application rates are not applicable to these exposure scenarios.								
Scenario #6 - Flagging									
Sprays	Lower application rates are not applicable to these exposure scenarios.								
Scenarios #7 Mixing/loading/applying liquids									
a) Low Pressure Handwand	Lower application rates are not applicable to these exposure scenarios.								
b) Backpack sprayer									
c) High pressure handwand (greenhouse)	0.040	0.020	5.00E-03	0.088	0.044	0.011	NF	NF	NF
Scenarios #8 Mixing/loading/applying (wetable powders)									
Low pressure handwand	Lower application rates are not applicable to these exposure scenarios.								
Scenarios #9 Loading/applying granules									
a) Belly Grinder	Lower application rates are not applicable to these exposure scenarios.								
b) Push-type spreader									

* These scenarios (1d, 1e, 2d, 2e, 4c, 4e, 4f, 4g, 7 and 8) have potential long-term exposure patterns.

- ^a Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractor; except for backpack sprayers. Chemical resistant gloves are included for the backpack assessment because the no glove scenario is not available. Baseline data are not available for aerial application.
- ^b Additional Personal Protective Equipment (PPE) to reduce dermal exposures = workers wearing coveralls over single layer clothing and chemical resistant gloves [Double Layer Clothing with Chemical Resistant Gloves (DLC, CRG)]. PPE data are not available for aerial application.
- ^c Engineering Controls = single layer clothing and no gloves (except where noted chemical resistant gloves -- because the no glove scenario is not available) and closed mixing systems and enclosed cab tractors.
- ^d Application rates are a range of representative and maximum rates values found in the diazinon labels. The following labels were used to determine the rates:
 (1) Wettable powders - EPA Reg. No. 100-460 (Diazinon 50 W). Min. rate represents beans, beets, broccoli, etc. Max. rate represents beans, beets, broccoli, etc.
 (2) Liquid formulations - EPA Reg. Nos. 100-784 (AG600 WBC) and 100-461 (AG500 emulsifiable solution). Min. rate represents apricots, beets, etc. Max. rate represents beans, etc. Rights-of-way rate is located on the EPA Reg. No. 100-461.
 (3) Granular - EPA Reg. No. 100-469 (Diazinon 14G) and Diazinon Granular Lawn Insect Control (2 percent).
 Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern. The granular lawn area is restricted to a maximum of 15,000 ft² (EPA Reg. No. 100-468).

Dermal Absorption Correction factor =100%; **NF** = Not Feasible; **ND** = No Data.

Application Rates

	Minimum	Typical	Maximum
Lb. a. i./Gallon	0.01	0.02	0.08

Table 24b. Occupational Handler Dermal Intermediate-term and Long-term MOEs for 0.2 - 5 lbs ai/gal. or Acre. * (Based on NOAEL = 0.02 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline ^{ad}			Maximum PPE ^{bd}			Engineering Controls ^{cd}		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
Scenario #1 - Mixing/loading liquids									
a) Aerial / Chemigation	5.52E-03	1.38E-03	3.45E-04	9.41E-01	2.35E-01	5.88E-02	1.9	4.65E-01	1.16E-01
b) Groundboom	2.41E-02	6.03E-03	1.51E-03	4.1	1.0	2.57E-01	8.1	2.0	5.09E-01
c) Airblast	4.83E-02	1.21E-02	3.02E-03	8.2	2.1	5.15E-01	16	4.1	1.0
d) Rights-of-Way Sprayer	4.83E-02	1.21E-02	3.02E-03	8.2	2.1	5.15E-01	16	4.1	1.0
e) High-pressure Handwand (Livestock Areas)	2.41E-03	2.41E-04	9.66E-05	4.12E-01	4.12E-02	1.65E-02	8.14E-01	8.14E-02	3.26E-02
Scenario #2 - Mixing/loading wettable powders									
a) Aerial / Chemigation	4.32E-03	1.08E-03	2.70E-04	1.23E-01	3.08E-02	7.69E-03	7.62E-01	1.90E-01	4.76E-02
b) Groundboom	1.89E-02	4.73E-03	1.18E-03	5.38E-01	1.35E-01	3.37E-02	3.3	8.33E-01	2.08E-01
c) Airblast	3.78E-02	9.46E-03	2.36E-03	1.1	2.69E-01	6.73E-02	6.7	1.7	4.17E-01
d) Rights-of-Way Sprayer	3.78E-02	9.46E-03	2.36E-03	1.1	2.69E-01	6.73E-02	6.7	1.7	4.17E-01
e) High-pressure Handwand (Livestock Areas)	1.89E-03	1.89E-04	7.57E-05	5.38E-02	5.38E-03	2.15E-03	3.33E-01	3.33E-02	1.33E-02
Scenario #3 - Loading granules									
Tractor-drawn broadcast spreaders	8.3	2.1	5.21E-01	2.06E+01	5.2	1.3	410	100	26
Scenarios #4 - Applying sprays / liquids									
a) Airblast	3.89E-01	9.72E-02	2.43E-02	6.36E-01	1.59E-01	3.98E-02	7.4	1.8	4.61E-01
b) Groundboom	5.0	1.2	3.13E-01	5.0	1.2	3.13E-01	14	3.5	8.75E-01
c) Paintbrush	7.78E-03	7.78E-04	3.11E-04	6.36E-02	6.36E-03	2.55E-03	NF	NF	NF
d) Airless Sprayer	4.61E-03	9.21E-04	1.84E-04	1.25E-02	1.25E-03	5.00E-04	NF	NF	NF
e) High-pressure Handwand (Livestock Areas)	3.89E-03	3.89E-04	1.56E-04	1.94E-02	1.94E-03	7.78E-04	NF	NF	NF
f) Handgun (lawn) Sprayer	2.4	0.61	0.15	10	2.5	0.62	NF	NF	NF
g) Rights-of-Way Sprayer	1.08E-01	2.69E-02	6.73E-03	4.83E-01	1.21E-01	3.02E-02	NF	NF	NF
h) Fixed-wing Aircraft	ND	ND	ND	ND	ND	ND	3.2	8.00E-01	2.00E-01
Scenarios #5 Applying granules									
Tractor-drawn broadcast spreaders	7.1	1.8	4.42E-01	17	4.2	1.0	33	8.3	2.1
Scenario #6 - Flagging									
Sprays	1.4	3.64E-01	9.09E-02	1.6	4.00E-01	1.00E-01	73	18	4.6
Scenarios #7 Mixing/loading/applying liquids									
a) Low Pressure Handwand	0.056	0.014	0.0035	15	3.8	0.95	NF	NF	NF
b) Backpack sprayer	2.2	0.56	0.14	3.5	0.87	0.22	NF	NF	NF
c) High pressure handwand (greenhouse)	2.00E-03	2.00E-04	8.00E-05	4.38E-03	4.38E-04	1.75E-04	NF	NF	NF
Scenarios #8 Mixing/loading/applying (wetable powders)									
Low pressure handwand	0.64	0.17	0.041	0.91	0.22	0.057	NF	NF	NF
Scenarios #9 Loading/applying granules									

Table 24b. Occupational Handler Dermal Intermediate-term and Long-term MOEs for 0.2 - 5 lbs ai/gal. or Acre. * (Based on NOAEL = 0.02 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline ^{ad}			Maximum PPE ^{bd}			Engineering Controls ^{cd}		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
<i>a) Belly Grinder</i>	0.56	0.14	0.035	1	0.25	0.062	NF	NF	NF
<i>b) Push-type spreader (no head & neck data available)</i>	0.64	0.17	0.04	2.6	0.64	0.17	NF	NF	NF

* These scenarios (1d, 1e, 2d, 2e, 4c, 4e, 4f, 4g, 7 and 8) have potential long-term exposure patterns.

- ^a Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractor; except for backpack sprayers. Chemical resistant gloves are included for the backpack assessment because the no glove scenario is not available. Baseline data are not available for aerial application.
- ^b Additional Personal Protective Equipment (PPE) to reduce dermal exposures = workers wearing coveralls over single layer clothing and chemical resistant gloves [Double Layer Clothing with Chemical Resistant Gloves (DLC, CRG)]. PPE data are not available for aerial application.
- ^c Engineering Controls = single layer clothing and no gloves (except where noted chemical resistant gloves -- because the no glove scenario is not available) and closed mixing systems and enclosed cab tractors.
- ^d Application rates are a range of representative and maximum rates values found in the diazinon labels. The following labels were used to determine the rates:
 (1) Wettable powders - EPA Reg. No. 100-460 (Diazinon 50 W). Min. rate represents beans, beets, broccoli, etc. Max. rate represents beans, beets, broccoli, etc.
 (2) Liquid formulations - EPA Reg. Nos. 100-784 (AG600 WBC) and 100-461 (AG500 emulsifiable solution). Min. rate represents apricots, beets, etc. Max. rate represents beans, etc. Rights-of-way rate is located on the EPA Reg. No. 100-461.
 (3) Granular - EPA Reg. No. 100-469 (Diazinon 14G) and Diazinon Granular Lawn Insect Control (2 percent).
 Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern. The granular lawn area is restricted to a maximum of 15,000 ft² (EPA Reg. No. 100-468).

Dermal Absorption Correction factor =100% . **NA** = not applicable; **NF** = Not Feasible; **ND** = No Data

Application Rates			
	Minimum	Typical	Maximum
lb a. i./Acre	0.25	1	4
lb a. i./Gallon	0.20	2	5

Risk estimates for all occupational inhalation handler exposure scenarios are included in tables 25(a) and 25(b).

Discussion of Tables 25(a) and 25(b)

Risks Based on Inhalation Exposures:

- The estimates of risk based on inhalation exposures in the tables below indicate that the MOEs are equal to, or greater than 300 at baseline for NO inhalation exposure scenarios, except for the following 2 exposure scenarios: 4 (f) applying sprays with handguns to lawns at 0.25 lbs ai/acre (MOE of 1700) and at 1 lb ai/acre (MOE of 430); and, 9 (b) loading and applying granules with push-type spreaders at 0.25 lb ai/acre (MOE of 390).
- With Additional PPE (with a half mask respirator), MOEs are equal to, or greater than 300 for the following 16 scenarios:
 - (1b) Mixing/loading liquids for groundboom applications, at a 0.25 lb ai/Acre application rate;
 - (1c) Mixing/loading liquids for airblast applications, at a 0.25 lb ai/Acre application rate;
 - (1d) Mixing/loading liquids for right-of-way applications, at a 0.25 lb ai/Acre application rate;
 - (1e) Mixing/loading liquids for high-pressure handwands in livestock areas, at 0.01 & 0.02 lbs ai/gallon application rates;
 - (3) Loading granules with tractor-drawn broadcast spreaders, at a 0.25 lb ai/Acre application rate;
 - (4a) Applying liquids with airblast sprayers, at a 0.25 lb ai/Acre application rate;
 - (4b) Applying liquids with groundboom sprayers, at 0.25 & 1 lb ai/Acre application rates;
 - (4c) Applying liquids with paint brushes, at 0.01 & 0.02 lbs ai/gallon application rates;
 - (4f) Applying liquids with hand-gun lawn sprayers, at all (0.25 ,1, & 4 lb ai/Acre) application rates;
 - (4g) Applying liquids with rights-of-way sprayers, at a 0.25 lb ai/Acre application rate;
 - (5) Applying granules with tractor-drawn broadcast spreaders, at a 0.25 lbs ai/Acre application rate;
 - (6) Flagging sprays (in support of aerial application), at a 0.25 lb ai/Acre application rate.
 - (7a) Mixing/Loading/Applying sprays with low pressure hand-wands, at 0.25 & 1 lb. ai/Acre application rates;

- (7b) Mixing/Loading/Applying sprays with backpack sprayers, at 0.25 & 1 lb. ai/Acre application rates;
- (9a) Loading/Applying granules with belly-grinders, at a 0.25 lb. ai/Acre application rate;
- (9b) Loading/Applying granules with push-type spreaders, at 0.25 & 1 lb. ai/Acre application rates;

Using Engineering Controls (closed mixing system or enclosed cabs with air filtrating systems in accordance with the Worker Protection Standard (WPS)), MOEs for the following 14 scenarios are equal to, or greater than 300:

- (1b) Closed Mixing/loading liquids for groundboom application at a 0.25 lb ai/Acre application rate;
- (1c) Closed Mixing/loading liquids for airblast application at 0.25, & 1 lb ai/Acre application rates;
- (1d) Closed Mixing/loading liquids for right-of-way application at 0.25, 1 lb ai/Acre application rates;
- (1e) Closed Mixing/loading liquids for high-pressure handwand in livestock areas at 0.01, & 0.02 lbs ai/gallon application rates;
- (2b) Closed Mixing/loading wettable powders for groundboom application at a 0.25 lb ai/Acre application rate;
- (2c) Closed Mixing/loading wettable powders for airblast application at a 0.25 lb ai/Acre application rate;
- (2d) Closed Mixing/loading wettable powders for right-of-way application at a 0.25 lb ai/Acre application rate;
- (2e) Closed Mixing/loading wettable powders for high-pressure handwand application in livestock areas at 0.01, & 0.02 lbs ai/gallon application rates;
- (3) Closed Loading granular, tractor-drawn broadcast spreaders at 0.25, & 1 lb ai/Acre application rates;
- (4a) Applying sprays with enclosed cab airblast sprayers at a 0.25 lb ai/Acre application rate;
- (4b) Applying sprays with enclosed cab groundboom sprayers at a 0.25 , & 1 lb ai/Acre application rates;

- (4h) Applying sprays with fixed-winged enclosed cockpits at a 0.25 lb ai/Acre application rate;
- (5) Applying granules with enclosed cab tractor-drawn broadcast spreaders at a 0.25 lbs ai/Acre application rate; and
- (6) Flagging sprays with enclosed cab vehicles (in support of aerial application) at 0.25, & 1 lb ai/Acre application rates.

For the following scenarios, MOEs are less than 300, after applying engineering controls (if feasible) and considering the minimum application rate:

- (1a) Mixing/loading liquid for aerial/chemigation applications;
- (2a) Mixing/loading wettable powders for aerial/chemigation applications;
- (4) Applying sprays/liquid with (d) airless sprayers and (e) high pressure hand-wands applications;
- (7) M/L/A liquids with (c) low pressure hand-wands; and
- (8) M/L/A wettable powders with low pressure hand-wands.

Table25a. Occupational Handler Inhalation MOEs for 0.01 - 0.08 lbs ai/gallon. (Based on LOAEL = 0.026 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline ^{ad}			Maximum PPE ^{bd}			Engineering Controls ^{cd}		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
Scenario #1 - Mixing/loading liquids									
a) Aerial / Chemigation	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									
c) Airblast									
d) Rights-of-Way Sprayer									
e) High-pressure Handwand (Livestock Areas)	150	76	19	760	380 ¹ 760 ²	95	2200	1100	270
Scenario #2 - Mixing/loading wettable powders									
a) Aerial / Chemigation	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									
c) Airblast									
d) Rights-of-Way Sprayer									
e) High-pressure Handwand (Livestock Areas)	4.2	2.1	0.53	21	11	2.6	760	380	95
Scenario #3 - Loading granules									
Tractor-drawn broadcast spreaders	Lower application rates are not applicable to these exposure scenarios.								
Scenarios #4 - Applying sprays / liquids									
a) Airblast	Lower application rates are not applicable to these exposure scenarios.								
b) Groundboom									
c) Paintbrush	130	65	16	650	320 ¹ 640 ²	81	NF	NF	NF
d) Airless Sprayer	5.5	2.7	0.68	27	13	3.4	NF	NF	NF
e) High-pressure Handwand (Livestock Areas)	2.3	1.2	0.29	11	5.7	1.4	NF	NF	NF
f) Handgun (lawn) Sprayer	Lower application rates are not applicable to these exposure scenarios.								
g) Rights-of-Way Sprayer									
h) Fixed-wing Aircraft									
Scenario #5 Applying granules									
Tractor-drawn broadcast spreaders	ND	ND	ND	ND	ND	ND	16	4.0	1.0
	Lower application rates are not applicable to these exposure scenarios.								
Scenario #6 - Flagging									
Sprays	Lower application rates are not applicable to these exposure scenarios.								
Scenario # 7 Mixing/loading/applying liquids									
a) Low Pressure Handwand	Lower application rates are not applicable to these exposure scenarios.								
b) Backpack sprayer									
c) High pressure handwand (greenhouse)	1.5	0.76	0.19	7.6	3.8	0.95	NF	NF	NF
Scenario # 8 Mixing/loading/applying (wetable powders)									

Table25a. Occupational Handler Inhalation MOEs for 0.01 - 0.08 lbs ai/gallon. (Based on LOAEL = 0.026 mg/kg/day.)									
Exposure Scenario Equipment /Usage	Baseline ^{ad}			Maximum PPE ^{bd}			Engineering Controls ^{cd}		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
Low pressure handwand	Lower application rates are not applicable to these exposure scenarios.								
Scenario # 9 Loading/applying granules									
a) Belly Grinder	Lower application rates are not applicable to these exposure scenarios.								
b) Push-type spreader									

^a Baseline data are not available for aerial application. Baseline inhalation exposure represents no respirator.

^b PPE inhalation exposure represents use of a respirator = dust/mist respirator applied to the baseline unit exposure (**Decreases the baseline unit exposure by 80%, if and only if, the worker has achieved a protective seal. This is accomplished by the worker being medically qualified to wear the specific respirator, fit tested to ensure a protective seal was achieved, and he/she has had the appropriate training to maintain the respirator in good condition in accordance with the American National Standards Institute (ANSI) and or OSHA 29CFR 1910.134.**)

^c Engineering Controls = single layer clothing and no gloves (except where noted chemical resistant gloves -- because the no glove scenario is not available) and closed mixing systems and enclosed cab tractors.

^d Application rates are a range of representative and maximum rates values found in the diazinon labels. The following labels were used to determine the rates:

(1) Wettable powders - EPA Reg. No. 100-460 (Diazinon 50 W). Min. rate represents beans, beets, broccoli, etc. Max. rate represents beans, beets, broccoli, etc.

(2) Liquid formulations - EPA Reg. Nos. 100-784 (AG600 WBC) and 100-461 (AG500 emulsifiable solution). Min. rate represents apricots, beets, etc. Max. rate represents beans, etc. Rights-of-way rate is located on the EPA Reg. No. 100-461.

(3) Granular - EPA Reg. No. 100-469 (Diazinon 14G) and Diazinon Granular Lawn Insect Control (2 percent).

Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern. The granular lawn area is restricted to a maximum of 15,000 ft² (EPA Reg. No. 100-468).

Daily inhalation Dose (mg/kg/day) = Dose{[(μg/lb ai) * (1mg/1000 μg) Conversion * Application Rate (lb ai/A or per gallon) * Acres or gallons treated]/70 kg BW}.

Margin Of Exposure (MOE) = Inhalation (for all time frequencies) LOAEL (0.026 mg/kg/day)/Daily Inhalation Dose. **The Inhalation Target MOE = 300; which does not exceed HED's level of concern.**

Application Rates

	<u>Minimum</u>	<u>Typical</u>	<u>Maximum</u>
Lb. a. i./Gallon	0.01	0.02	0.08

NF = Not Feasible; ND = No Data.

Table 23b. Occupational Handler Inhalation MOEs for 0.2 - 5 lbs at/gallon of Acre. (Based on LOAEL = 0.026 mg/kg/day.)									
Exposure Scenario Equipment / Usage	Baseline ^a			Maximum PPE ^b			Engineering Controls ^c		
	Min.	Typical	Max.	Min.	Typical	Max.	Min.	Typical	Max.
Scenario #1 - Mixing/loading liquids									
a) Aerial / Chemigation	17	4.3	1.1	87	22	5.4	250	63	16
b) Groundboom	76	19	4.7	380	95	24	1100	270	69
c) Airblast	150	38	9.5	760	190 /380	47	2200	550	140
d) Rights-of-Way Sprayer	150	38	9.5	760	190 /380	47	2200	550	140
e) High pressure Handwand (Livestock Areas)	7.6	7.6 E-01	3.0 E-01	38	3.8	1.5	110	11	4.4
Scenario #2 - Mixing/loading wettable powders									
a) Aerial / Chemigation	0.48	1.2 E-01	2.0 E-02	2.4	6.0 E-01	1.5 E-01	87	22	5.4
b) Groundboom	2.1	5.3 E-01	1.3 E-01	11	2.7	6.6 E-01	380	95	24
c) Airblast	4.2	1.1	2.7 E-01	21	5.3	1.3	760	190	47
d) Rights-of-Way Sprayer	4.2	1.1	2.7 E-01	21	5.3	1.3	760	190	47
e) High pressure Handwand (Livestock Areas)	2.1 E-01	2.1 E-02	8.5 E-03	1.1	1.1 E-01	4.2 E-02	38	3.8	1.5
Scenario #3 - Loading granules									
Tractor-drawn broadcast spreaders	53	13	3.4	270 /540	67	17	2700	670	170
Scenarios #4 - Applying sprays / liquids									
a) Airblast	40	10	2.5	200/400	51	12	400	100	25
b) Groundboom	120	31	7.7	600	150/300	38	2100	530	130
c) Paintbrush	6.5	6.5 E-01	2.6 E-01	32	3.2	1.3	NF	NF	NF
d) Airless Sprayer	2.7 E-01	2.7 E-02	1.1 E-02	1.3	1.3 E-01	5.3 E-02	NF	NF	NF
e) High pressure Handwand (Livestock Areas)	1.1 E-01	1.1 E-02	4.6 E-03	5.7 E-01	5.7 E-02	2.3 E-02	NF	NF	NF
f) Handgun (tawn) Sprayer	1700	430	110	8700	2200	540	NF	NF	NF
g) Rights-of-Way Sprayer	47	12	2.9	230/460	58	15	NF	NF	NF
h) Fixed-wing Aircraft	ND	ND	ND	ND	ND	ND	340	77	19
Scenario #5 Applying granules									
Tractor-drawn broadcast spreaders	76	19	4.7	380/760	95/90	24/50	410	100	26
Scenario #6 - Flagging									
Sprays	59	15	3.7	300/600	74/150	10/40	3000	740	190
Scenario #7 Mixing/loading/applying liquids									
a) Low Pressure handwand	240	61	15	1200	300/610	76/152	NF	NF	NF
b) Backpack sprayer	240	61	15	1200	300/610	76/152	NF	NF	NF
c) High pressure handwand (greenhouse)	7.6 E-02	7.6 E-03	3.0 E-03	3.8 E-01	3.8 E-02	1.5 E-02	NF	NF	NF
Scenario #8 Mixing/loading/applying (wettable powders)									
Low pressure handwand	6.6	1.7	0.41	33/66	8.3/17	2.1/4.1	NF	NF	NF
Scenario #9 Loading/applying granules									
a) Belly Grinder	120	29	7.3	587	150/290	37/72	NF	NF	NF
b) Push-type spreader (No head & neck data available)	390	98	24	5900	490	120/240	NF	NF	NF

^a

Baseline data are not available for aerial application. Baseline inhalation exposure represents no respirator.

^b

PPE inhalation exposure represents use of a respirator = dust/mist respirator applied to the baseline unit exposure[(Decreases the baseline unit exposure by: ¹ = 80% (1/4-Mask-Respirator) and ² = 90% (1/2-Mask-Respirator), if and only if, the worker has achieved a protective seal. This is accomplished by the worker being medically qualified to wear the specific respirator, fit tested to ensure a protective seal was achieved, and he/she has had the appropriate training to maintain the respirator in good condition in accordance with the American National Standards Institute (ANSI) and or OSHA 29CFR 1910.134).

- ^c Engineering Controls = single layer clothing and no gloves (except where noted chemical resistant gloves -- because the no glove scenario is not available) and closed mixing systems and enclosed cab tractors.
- ^d Application rates are a range of representative and maximum rates values found in the diazinon labels. The following labels were used to determine the rates:
- (1) Wettable powders - EPA Reg. No. 100-460 (Diazinon 50 W). Min. rate represents beans, beets, broccoli, etc. Max. rate represents beans, beets, broccoli, etc.
 - (2) Liquid formulations - EPA Reg. Nos. 100-784 (AG600 WBC) and 100-461 (AG500 emulsifiable solution). Min. rate represents apricots, beets, etc. Max. rate represents beans, etc. Rights-of-way rate is located on the EPA Reg. No. 100-461.
 - (3) Granular - EPA Reg. No. 100-469 (Diazinon 14G) and Diazinon Granular Lawn Insect Control (2 percent).
- Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern. The granular lawn area is restricted to a maximum of 15,000 ft² (EPA Reg. No. 100-468).
- Daily Inhalation Dose (mg/kg/day) = [(Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion * Application Rate (lb ai/A or per gallon) * Acres or gallons treated /day) / 70kg bw].
- Margin Of Exposure (MOE) = Inhalation (for all time frequencies) LOAEL (0.026 mg/kg/day)/Daily Inhalation Dose. *The **Inhalation Target MOE = 300; which does not exceed HED's level of concern.***

Application Rates

	Minimum	Typical	Maximum
lb a. i./Acre	0.25	1	4
lb a. i./Gallon	0.20	2	5

NF = Not Feasible; **ND** = No Data; **NA** = Not applicable.

(ii). Occupational Risk Estimates from Adding Dermal and Inhalation Exposure.

Because the same toxicity endpoint (i.e., RBC cholinesterase inhibition) is applicable to both inhalation and dermal risk assessments, and because dermal and inhalation exposures may occur simultaneously, it is appropriate to add these exposures together to obtain a total risk estimate for occupational exposure. As seen above, at various label application use rates, several inhalation exposure scenarios have MOEs >300. For intermediate-term dermal exposure, only one scenario with engineering controls has risk estimates (MOEs) greater than or equal to 100. For short-term dermal exposures, 1 scenario using baseline protection, 7 scenarios using additional PPE, and 13 scenarios using engineering controls have MOEs >100.

The formula used to combine the dermal and inhalation risks is the Aggregate Risk Index, because the dermal and inhalation exposures have different acceptable Margins of Exposure (MOEs); for dermal MOEs at or greater than 100, and for inhalation, all time periods, MOEs at or greater than 300:

The formula used to combine the dermal and inhalation risks is:

$$\begin{aligned} \text{ARI} &= \text{MOE}_{\text{calculated}} / \text{MOE}_{\text{acceptable}} \\ \text{ARI}_{\text{dermal}} &= \text{MOE}_{\text{calculated dermal}} / \text{MOE}_{\text{acceptable dermal}} \\ \text{ARI}_{\text{inhalation}} &= \text{MOE}_{\text{calculated inhalation}} / \text{MOE}_{\text{acceptable inhalation}} \end{aligned}$$

The formula used to combine the dermal and inhalation risks is:

$$\text{Aggregate Risk Index (ARI)} = 1 / [1/\text{ARI}_{\text{dermal}} + 1/\text{ARI}_{\text{inhalation}}]$$

Using this formula, the combined dermal and inhalation risks were calculated for exposure scenarios for which maximum PPE and/or engineering controls were available to control both dermal and inhalation exposures. Risk estimates are given in Tables 26 and 27 below, all ARIs below 1, exceed HED's level of concern.

In summary, once dermal and inhalation exposures are combined, 10 major use scenarios (9 major short-term exposure scenarios and one intermediate-term exposure scenario) have Aggregate Risk Indices (ARIs) greater than or equal to 1.0, and do not exceed HED's level of concern. HED combined dermal risk estimates for those dermal exposure scenarios which individually have MOEs equal to or greater than 100 with the appropriate inhalation risk estimate for the same exposure scenario. Since all other dermal exposure scenarios result in MOEs less than 100, aggregating dermal and inhalation risks for these scenarios will also result in these scenarios having calculated ARIs below 1.0, indicating a concern. The 10 exposure scenarios for which combined dermal plus inhalation risk estimates result in ARIs above or equal to 1.0 are:

With PPE (for short-term dermal and inhalation exposures):

- 4 (f) Applying sprays/liquid with hand-gun lawn sprayers, @ 0.25 lbs ai/Acre;
- 7 (a) M/L/A liquids with low pressure hand-wands, @ 0.25 lbs ai/Acre;

With Engineering Controls (for short-term dermal and inhalation exposures):

- 1(c) Mixing/loading liquids for airblast sprayers, @ 0.25 lbs ai/Acre
- 1(d) Mixing/loading liquids for rights-of-way sprayers, @ 0.25 lbs ai/Acre

- 1(e) Mixing/loading liquids for high pressure hand-wands, @ 0.01 lbs ai/gallon
- 3) Loading granules for tractor-drawn broadcast spreaders, @ 0.25/1.0 lbs ai/Acre
- 4(b) Applying sprays/liquids with groundboom sprayers, @ 0.25 lbs ai/Acre
- 5) Applying granules with tractor-drawn broadcast spreaders, @ 0.25 lbs ai/Acre
- 6) Flagging in support of aerial spray applications, @ 0.25 and 1.0 lbs ai/Acre

With Engineering Controls

(for intermediate- and long-term dermal and inhalation exposures):

- 3) Loading granules for tractor-drawn broadcast spreaders, @ 0.25 lbs ai/Acre

Table 26. Combined Risk Estimates for Short-term Dermal and Inhalation Exposure Scenarios (MOEs).			
Scenarios	Dermal Risk Estimates	Inhalation Risk Estimates	Combined Risk Estimates (ARIs)
With Baseline Protection			
3) @ 0.25 lbs ai/Acre	100	53	0.15
With Additional PPE			
1(c) @ 0.25 lbs ai/Acre	100	760	0.72
1(d) @ 0.25 lbs ai/Acre	100	760	0.72
1(e) @ 0.01 lbs ai/gallon	100	760	0.72
3) @ 0.25 lbs ai/Acre	260	270	0.67
4 (f) @ 0.25 lbs ai/Acre	120	8700	1.15
5) @ 0.25 lbs ai/Acre	210	380	0.79
7 (a) @ 0.25 lbs ai/Acre	190	1200	1.3
With Engineering Controls			
1(b) @ 0.25 lbs ai/Acre	100	1100	0.79
1(c) @ 0.25 lbs ai/Acre	200	2200	1.6
1(d) @ 0.25 lbs ai/Acre	200	2200	1.6
1(e) @ 0.01/0.02 lbs ai/gallon	200 / 100	2200 / 1100	1.6 / 0.79
3) @ 0.25/1.0/4.0 lbs ai/Acre	5200 / 1300 / 320	2700 / 670 / 170	7.7 / 1.9 / 0.48
4(b) @ 0.25 lbs ai/Acre	180	2100	1.4
5) @ 0.25/1.0 lbs ai/Acre	420 / 100	410 / 100	1.03 / 0.25
6) @ 0.25/1.0 lbs ai/Acre	910 / 230	3000 / 740	4.8 / 1.2

Table 27. Combined Risk Estimates for Intermediate- and Long-term Dermal and Inhalation Exposure Scenarios (MOEs).			
Scenario w/ Engineering Controls	Dermal Risk Estimate	Inhalation Risk Estimate	Combined Risk Estimate
3 @ 0.25 lbs ai/Acre	410	2700	2.8
3 @ 1.0 lbs ai/Acre	100	670	0.69

(e). Occupational Postapplication Risk Estimates

Short-term and intermediate-term postapplication occupational exposures may occur dermally, but not through inhalation for typical outdoor harvesting activities. However, occupational dermal and inhalation exposures may occur from indoor uses of diazinon in enclosed spaces, such as registered uses on greenhouse ornamentals. Postapplication exposures of 1 to 7 days are considered short-term; postapplication exposures of 1 week to several weeks are considered intermediate-term. Risk estimates (MOEs) and associated reentry intervals (REIs) for occupational postapplication short-term and intermediate-term dermal exposures assuming 100% dermal absorption, are provided in Table 28. Safe REIs are achieved when the MOE is 100 for short- and intermediate-term dermal exposures. Risk estimates and REIs were calculated for tree crops (citrus), grapes (using citrus data), and low potential exposure crops (using cabbage data). Low potential exposure crops include low-growing crops like lettuce and broccoli. The risk estimates are based on dislodgeable foliar residue (DFR) data for tree crops and cabbage. The risk estimates (MOEs) and REIs are based on harvesting activities with transfer coefficients of 10,000 cm²/hour for tree crops (citrus), 15,000 cm²/hour for grapes, and 2,500 cm²/hour for crops with a low exposure potential. DFR values are for diazinon only; no metabolites were included in the analyses. DFR values and calculated dermal doses for the three crop types at different intervals are provided in Table 28.

The dermal dose was calculated through the following equation:

$$\text{Dermal dose in (mg/kg/day)} = \{ [DFR (\mu\text{g/cm}^2)] * \text{transfer coefficient } (T_c) * 8 \text{ hours worked per day} * 0.001 \text{ mg}/\mu\text{g conversion} * 1.0 (100\% \text{ dermal absorption correction factor}) / 70 \text{ kg body weight} \}.$$

The Margin of Exposure was calculated as:

$$MOE = NOEL \text{ (mg/kg/day)} / \text{Dermal Dose (mg/kg/day)},$$

where for short-term exposures defined as 0 to 7 days, a NOAEL of 0.25 mg/kg/day was used; for 8 to 9 day exposures, both short-term and intermediate-term toxicity endpoints were used, and for intermediate-term exposures of 13 to 23 days duration, a NOAEL of 0.02 mg/kg/day was used.

Table 28 reports a range of MOEs for various days after treatment (DATs) assuming 100 percent dermal absorption and various DFR values for trees, grapes, and low potential exposure crops. Available DFR data on citrus were adjusted by a factor of 3 to estimate DFR values on grapes treated at 1 lb ai/A, the maximum labeled rate. Residue levels from submitted DFR studies were used to extrapolate DFR values below the limit of detection (< LOD). For tree crops, based on the maximum application rate (3 lb ai/A), short- and intermediate-term MOEs are less than 12 for residues greater than or equal to the LOD. Extrapolating, DFR values for tree crops reach ½ the LOD (0.002 µg/cm²) at 15 days after treatment, and the MOE is 6.2. HED notes that safe reentry intervals (REIs) could not be established for short- and intermediate-term dermal exposures incurred through harvesting activities associated with tree crops.

For grapes, based on the maximum application rate (1 lb ai/A), short- and intermediate-term MOEs are less than 25 for residues greater than or equal to the LOD. Extrapolating, DFR values for grapes reach ½ the LOD (0.002 µg/cm²) at 11 days after treatment, and the MOE is 5.6. HED notes that safe reentry intervals (REIs) could not be established for short- and intermediate-term

dermal exposures incurred through harvesting activities associated with grapes.

For the low potential exposure crops (e.g., cabbage, lettuce), based on the typical application rate of 2.0 lb ai/A, MOEs for intermediate-term exposures are less than 100 for residues greater than or equal to the LOD. Extrapolating, DFR values for low potential exposure crops reach $\frac{1}{2}$ the LOD ($0.001 \mu\text{g}/\text{cm}^2$) at 16 days after treatment, and the MOE is 62. HED notes that safe reentry intervals (REIs) could be established for short-term dermal exposures at 8 to 9 days after treatment at 2.0 lb ai/acre (MOEs 96 to 120) incurred through harvesting activities associated with cabbage, broccoli, and low-growing crops. HED also notes that a safe REI could be established at 3 days after treatment for low potential exposure crops based on a minimum treatment rate of 0.25 lb ai/acre and a calculated MOE of 170.

Essentially, for all postapplication dermal exposure scenarios associated with tree crops and grapes, DFR levels must be extrapolated below $\frac{1}{2}$ of the LOD before MOEs greater than or equal to 100 can be achieved. However, for low-growing crops, a MOE of 96 is achieved for short-term dermal exposures 8 days after treatment, and a MOE of 62 is achieved for intermediate-term dermal exposures 16 days after treatment at a treatment rate of 2.0 lbs ai/acre. However, a safe REI could be established at 3 days after treatment for low potential exposure crops based on a treatment rate of 0.25 lb ai/acre and a calculated MOE of 170.

The information submitted by the registrant to support a 3.85 percent dermal absorption factor is insufficient (DP Barcode: D238960, November 30, 1999). The study submitted had the following citation: Wester, R.C., et al., "Percutaneous absorption of diazinon in humans", Food Chemistry and Toxicology, Volume 31, No. 8, pp. 569-572, 1993. Specifically, detailed information on the material tested, material dosed, method of application, sample collection, observations and control of the human test subjects, and analysis of data were lacking. HED recommends the appropriate information be organized, properly formatted, and resubmitted to the Agency for review before a determination as to the validity of the dermal absorption factor can be considered further.

Table 28 . Occupational Post-application Short- and Intermediate-term Risks and Estimated REIs for Diazinon – Assuming 100 percent Absorption									
Days After Treatment (DAT)	Tree Crops - 3 lbs ai/A ^a			Grapes - 1.0 lb ai/A ^a			Low Potential Exposure - typical- mid range rate of 2.0 lb ai/A ^a		
	DFR ($\mu\text{g}/\text{cm}^2$) ^b	Dermal Dose (mg/kg/day) ^c	MOE ^d	DFR ($\mu\text{g}/\text{cm}^2$) ^b	Dermal Dose (mg/kg/day) ^c	MOE ^d	DFR ($\mu\text{g}/\text{cm}^2$) ^b	Dermal Dose (mg/kg/day) ^c	MOE ^d
0	0.12	0.14	1.8	0.040	0.069	3.6	0.080	0.023	11
1	0.093	0.11	2.4	0.031	0.053	4.7	0.062	0.018	14
2	0.069	0.079	3.2	0.023	0.039	6.3	0.046	0.013	19
3	0.0537	0.061	4.1	0.0179	0.031	8.1	0.0358	0.010	25
4	0.0411	0.047	5.3	0.0137	0.023	11	0.0274	0.008	31
5	0.0315	0.036	6.9	0.0105	0.018	14	0.0210	0.006	42
6	0.024	0.027	9.1	0.008	0.014	18	0.016	0.0045	56
7	0.0183	0.021	12	0.0061	0.010	24	0.0122	0.0035	71
8	0.0140	0.016	16 (S)/1.2(I)	0.00468	0.0080	31(S)/2.5(I)	0.0094	0.0026	96(S)/7.7(I)
9	0.0107	0.012	21 (S)/1.6(I)	0.00358	0.0061	41(S)/3.3(I)	0.0072	0.0020	120(S)/10(I)
10	0.0082	0.0094	2.1	0.00274	0.0047	4.3	0.0055	0.0016	12
11	0.0063	0.0072	2.8	0.0021	0.0036	5.6	0.0042	0.0012	17
13	0.0036	0.0042	4.8	0.0012	0.0021	9.6	0.0024	0.0007	29
15	0.0022	0.0025	6.2	0.00072	0.0012	16	0.0014	0.00041	49
16	0.0016	0.0019	11	0.00055	0.00094	21	0.0011	0.00032	62
19	0.00072	0.00082	8.1	0.00024	0.00041	47	0.00048	0.00014	140
22	0.00033	0.00038	53	0.00011	0.00019	110	-	-	-
25	0.00015	0.00017	120	0.000049	0.000084	240	-	-	-

Note: Rounding errors, calculations were performed on a spreadsheet.

^a = Activity is based on harvesting with transfer coefficients (T_c) of 10,000 cm^2/hour for tree crops, 15,000 cm^2/hour for grapes, and 2,500 cm^2/hour for low exposure potential crops.

^b = Citrus DFR values (MRID 404666-01; LOD = 0.004 $\mu\text{g}/\text{cm}^2$) used for tree crops and grapes. Cabbage DFR values (MRID 402029-02; LOD = 0.002 $\mu\text{g}/\text{cm}^2$) are used to represent low potential exposure crops.

^c = Dermal Dose (mg/kg/day) = {[DFR ($\mu\text{g}/\text{cm}^2$)] * transfer coefficient (T_c) * 8 hours worked per day * 0.001 mg/ μg conversion * 1.0 (100% dermal absorption correction factor) / 70 kg body weight}.

^d = MOE = NOEL (mg/kg/day)/Dermal Dose (mg/kg/day), where for short-term (0-7 days) dermal, NOAEL = 0.25mg/kg/day was used; for days 8, and 9-both Short-term(S) and Intermediate-term (I) toxicity endpoints, were used, for intermediate-term (13-23 days where applicable), NOEL = 0.02 mg/kg/day was used.

Uncertainties in the above analysis include: the use of 100 percent dermal absorption; the use of a linear extrapolation applied to the DFR values from the study application rate (1 lb ai/A) to the maximum labeled rate (3 lbs ai/A) for tree crops; and the use of the citrus DFR values once adjusted for differences in application rates between citrus and grapes to estimate exposure from grapes. The use of 100 percent dermal absorption may overestimate the risks. The effect of extrapolating the citrus DFR data to a higher application rate and using it to represent grape leaves is unknown and may under- or overestimate the actual residue levels. An acceptable dermal absorption study would allow refinement of the dermal exposure and risk estimates. The significant difference between the current REI on the diazinon labels (24 hours), that listed for California (5 days for some crops), and those estimated by the Agency is attributed to HED's use of plasma ChE as the toxicological endpoint (i.e., short-term of 0.25 mg/kg/day, and intermediate-term of 0.02 mg/kg/day and an uncertainty factor of 100).

Risk estimates for short-term, occupational, postapplication, dermal exposures to diazinon as a result of greenhouse uses were based on data available from registrant-submitted studies (MRIDs 44348802, -03, -04, & -06). Although the studies were not considered acceptable as per Agency test guidelines, the information provided was used to provide risk estimates for postapplication exposures to diazinon in greenhouses. Risk estimates for occupational postapplication inhalation exposures to diazinon as a result of registered greenhouse uses were based on diazinon-specific data collected on airborne residues of diazinon in greenhouses after application to container greenhouse plants (MRID 44348804). Because of the quality of the data available, the risk estimates are considered unrefined. A detailed review of these data is contained in Attachment VI.

From the information submitted, the registrant extrapolated to calculate a theoretical dislodgeable foliar residue (DFR) value of 2.7 $\mu\text{g}/\text{cm}^2$ for residues of diazinon immediately after treatment (0 hours) at the maximum treatment rate of 1.5 lb ai/100 gallons of spray applied. The measured DFR value (from MRID 44348802) 12 hours after treatment was 0.44 $\mu\text{g}/\text{cm}^2$ for an estimated treatment rate of 0.58 lb ai/100 gallons sprayed. The Agency used these values to estimate short-term postapplication, dermal exposures for greenhouse workers. The Agency also used a transfer coefficient of 9,000 cm^2/hour , which is considered appropriate for the plants and activities involved. The restricted reentry interval (REI) for workers reentering greenhouses after diazinon use is 12 hours.

The Agency calculate postapplication occupational short-term dermal exposure using the following assumptions: 100 % dermal absorption, eight hours worked, a 70 kg body weight, the same transfer coefficient as provided by the registrant, 9,000 cm^2/hour , a DFR value of 2.7 $\mu\text{g}/\text{cm}^2$ at 0 hours after treatment and a DFR value of 0.44 $\mu\text{g}/\text{cm}^2$ 12 hours after treatment, and the Agency's selected short-term dermal NOAEL of 0.25 mg/kg/day. Based on the Agency's assumptions, using either a DFR value measured immediately after treatment or a DFR value measured at the 12 hour restricted reentry interval, the calculated MOE for short-term dermal exposure is less than 1. Even if a 3.85% dermal absorption was assumed (as per the registrant's recommendation) with a transfer coefficient of 9,000 cm^2/hour , a dislodgeable foliar residue of either 2.7 $\mu\text{g}/\text{cm}^2$ (0 hours after treatment) or 0.44 $\mu\text{g}/\text{cm}^2$ (12 hours after treatment), a shorter exposure period of 6 hours, a 60 kg body weight, and a NOAEL of 0.25 mg/kg/day, the calculated MOE is below 20. Based on either set of assumptions given above, the MOE for short-term dermal exposure at the 12 hour

REI for greenhouse uses is below 100 and exceeds HED's level for concern.

For short-term dermal postapplication exposure, 12 hours after treatment at 1.5 lb ai/100 gallons sprayed, the following calculations were used:

$$0.44 \mu\text{g}/\text{cm}^2 \text{ (DFR)} * 9,000 \text{ cm}^2/\text{hr} * 8 \text{ hours worked} * 1(100\% \text{ dermal absorption}) \div 70\text{kg} = 0.45 \text{ mg/kg/day}$$

$$\text{MOE (short-term dermal exposure)} = 0.25 \text{ mg/kg/day} \div 0.45 \text{ mg/kg/day} = 0.55$$

The most obvious difference in the approach taken by the Agency versus the registrant is the Agency's assumption of 100% dermal absorption. The registrant's rationale for reducing absorption below 100% is based on a 3.85% dermal absorption factor and their belief that in addition, the long-sleeved shirts and gloves worn by the workers would reduce the potentially absorbed dose (as modified by 3.85% dermal absorption) by more than 90%. However, reentry workers are not required to wear gloves or any other protective clothing other than long-sleeved shirts, long pants, socks and shoes. In their independent risk assessment for postapplication dermal exposures to diazinon in greenhouses, the registrant also used a short-term dermal NOAEL of 1 mg/kg/day taken from a 21-day dermal study in rabbits. The Agency has concluded that this is an inappropriate endpoint to use in risk assessment because of the difference in species sensitivity between rabbits and rats regarding the detoxification of diazinon applied dermally, i.e., rabbits detoxify diazinon applied to the skin more rapidly than the other test species (rats and dogs).

Intermediate-term and long-term dermal exposures are expected to result in even lower MOEs because the same dose as calculated for short-term exposures would be compared to the intermediate-term dermal NOAEL of 0.02 mg/kg/day. The resulting risk estimates for intermediate dermal exposures to diazinon residues in greenhouses are expected to be above HED's level of concern.

Postapplication occupational inhalation exposure from greenhouse uses is based on data from a diazinon-specific study (MRID 44348804) in which the application rate was stated to be 1.0 lb ai/100 gallon sprayed. [The Agency estimates that the application rate was really 0.58 lb ai/100 gallons sprayed.] Airborne diazinon residues were monitored using personal air-sampling pumps calibrated to 0.5 liters per minute that were connected to sampling tubes containing a glass fiber filter, a sorbent, and polyurethane foam. Three air-sampling tubes were placed in the workers breathing zone. Samples were collected prior to application and at five intervals after application. Measured average diazinon residues ranged from $39 \mu\text{g}/\text{m}^3$ at 1.4 to 2.3 hours after application to $0.8 \mu\text{g}/\text{m}^3$ at 66 to 75 hours after application. At 12 hours posttreatment, residue values were $16 \mu\text{g}/\text{m}^3$.

Assuming the treatment rate used in the study was 1.0 lb ai/100 gallons sprayed, and using a ratio ($39 \mu\text{g}/\text{m}^3/1.0 \text{ lb ai} = x \mu\text{g}/\text{m}^3/1.5 \text{ lb ai}$) to linearly extrapolate to the expected residues following an application at the maximum rate of 1.5 lbs. ai/100 gallons sprayed, the expected residue would be $59 \mu\text{g}/\text{m}^3$ 1 hour after treatment at 1.5 lb ai/100 gallons sprayed, and $22.62 \mu\text{g}/\text{m}^3$ 1 hour after treatment following an application at the 0.58 lbs. ai/100 gallon sprayed. Extrapolating further, airborne residue values 12 hours after an application at 0.58 lbs. ai/100 gallon sprayed are expected to be $9 \mu\text{g}/\text{m}^3$.

The Agency has elected to calculate postapplication occupational inhalation exposure using the following assumptions: assuming 15.2 m^3 as the volume of air respired by a human adult during an

8 hour period (1997 Exposure Factors Handbook), a 70 kg body weight, an airborne residue value of $16 \mu\text{g}/\text{m}^3$ (12 hours after treatment at 1.5 lb ai/100 gallons sprayed), and $9 \mu\text{g}/\text{m}^3$ (12 hours after treatment at 0.58 lb ai/100 gallons sprayed), and a LOAEL of 0.026 mg/kg/day. Using the above assumptions, inhalation exposure 12 hours after an application rate of 1.5 lbs. ai/ 100 gallons sprayed was calculated to be 0.0035 mg/kg/day resulting in a MOE of 8, which exceeds HED's level for concern. Using the above assumptions, inhalation exposure 12 hours after an application rate of 0.58 lbs. ai/100 gallons sprayed was calculated to be 0.002 mg/kg/day resulting in a MOE of 13, which exceeds HED's level for concern.

The following equations were used:

Inhalation exposure 12 hours after application at 1.5 lb ai/100 gallons sprayed:
 $(16 \mu\text{g}/\text{m}^3 * 15.2 \text{ m}^3) \div 70\text{kg} = 3.5 \mu\text{g}/\text{kg}/\text{day} * 0.001 \text{ mg}/\mu\text{g} = 0.0035 \text{ mg}/\text{kg}/\text{day}$

$\text{MOE (inhalation exposure)} = 0.026 \text{ mg}/\text{kg}/\text{day} \div 0.0035 \text{ mg}/\text{kg}/\text{day} = 8$

Inhalation exposure 12 hours after application at 0.58 lb ai/100 gallons sprayed:
 $(9 \mu\text{g}/\text{m}^3 * 15.2 \text{ m}^3) \div 70\text{kg} = 1.9 \mu\text{g}/\text{kg}/\text{day} * 0.001 \text{ mg}/\mu\text{g} = 0.002 \text{ mg}/\text{kg}/\text{day}$

$\text{MOE (inhalation exposure)} = 0.026 \text{ mg}/\text{kg}/\text{day} \div 0.002 \text{ mg}/\text{kg}/\text{day} = 13$

All calculated postapplication inhalation exposures of workers reentering greenhouses that have been treated with diazinon from application rates of 0.58 to 1.5 lb ai/100 gallon sprayed 12 hours after treatment have MOEs less than 15, and exceed HED's level of concern for inhalation exposures. The established REI for greenhouse uses is 12 hours.

(f.) Residential Exposure and Risk Estimates

(i). Homeowner Handlers Exposure

Diazinon also has a wide variety of homeowner uses including lawn treatments, spot treatments, and indoor crack and crevice treatments. Diazinon is applied by many methods including spray equipment, and granular spreaders. All residential handler use patterns are considered to provide short-term exposures. HED has conducted screening-level exposure and risk assessments for 7 residential exposure scenarios resulting from registered uses of diazinon. Because there are no homeowner handler residential exposure data available, the residential risk assessments are based on the Residential Standard Operating Procedures (SOPs), December 1997 version, and HED standard assumptions for the area treated per day. Based on the available data, 100% dermal absorption was assumed for those assessments involving dermal exposures. The unit dermal and inhalation exposures for short-term exposures, and the caveats and parameters specific to each residential handler exposure scenario are summarized in Table 29. Risk estimates are provided in Tables 30(a), 30 (b), and 30(c) based on MRID 44959101. The restriction on current labels for non-agricultural uses that are out of the scope of the Worker Protection Standard is, *“Do not enter or allow entry into treated areas until sprays have dried. Do not permit children or pets to go onto sprayed grass until spray has completely dried.”*

The 7 residential handler scenarios (R) are as follows:

1R. Applying liquids with a paintbrush.

- 2R. Applying liquids with an airless sprayer.
- 3R. Mixing/loading/applying liquids with a low pressure handwand.
- 4R. Mixing/loading/applying liquids with a backpack sprayer.
- 5R. Mixing/loading/applying liquids with a garden hose-end sprayer.
- 6R. Loading/applying granules with a belly grinder.
- 7R. Loading/applying with a push-type spreader.

Residential exposure assumptions are from HED's Draft Residential Standard Operating Procedures (SOPs), December 1997 version. The Residential Unit Exposure numbers are derived from the Pesticide Handler Exposure Database (PHED) Version 1.1. Baseline Dermal Unit Exposures are based on homeowner applicators wearing short sleeve shirts and short pants, and no gloves (sss, sp, ng) open mixing/loading; and open cab tractor; except for backpack sprayers. Chemical resistant gloves are included for the backpack assessment because the "no glove" scenario is not available; therefore a 90% protection factor (PF) was used. To account for the "no glove" scenario, a back calculation was conducted to obtain the appropriate unit exposure value for a no glove scenario for backpack application. Baseline inhalation exposure estimates assume no respirator.

Table 29 . Diazinon Handler Residential SOP (Derived from PHED V1.1) Unit Exposures ^a											
Exposure Scenario Equipment / Usage	Dermal Unit Exposure (mg/lb ai) (dermal+hands)	Dermal Data Confid.	Derm. Grades	Derm. Repli.	Hand Grade	Hand Repli.	Clothing ^b Scenario	Inhalatn. Unit Exposure (ug/lb ai)	Inhalatn. Data Confid.	Inhalatn. Grades	Inhalation Repli.
Applicator											
<i>Applying sprays / liquids</i>											
Scenario # 1R Paintbrush	230	Low	C	14-15	B	15	SSS, SP, NG	280	Medium	C	15
Scenario # 2R Airless Sprayer	79	High	B	15	B	15	SSS, SP, NG	830	Medium	C	15
Mixer/Loader/Applicator											
<i>Mixing/loading/applying liquids</i>											
Scenario # 3R Low Pressure Handwand	100	Low	ABC	8-9	All	70	SSS, SP, NG	30	Medium	ABC	80
Scenario # 4R Backpack sprayer	5.1	Low	AB	9-11	C	11	SSS, SP, NG	30	Low	A	11
Scenario # 5R Garden hose-end sprayer	30	Low	C	8	E	8	SSS, SP, NG	9.5	Low	C	8
<i>Loading/applying granules</i>											
Scenario # 6R Belly Grinder	110	Medium	ABC	20-45	ABC	23	SSS, SP, NG	62	High	AB	40
Scenario # 7R Push-type spreader (Head& neck data is not available)	3	Low	C	0-15	C	15	SSS, SP, NG	6.3	High	B	15

(ii). Homeowner Handler Risk Estimates

The target margin of exposure (MOE) is 100 for handler short-term dermal residential exposures to diazinon by homeowner handler/applicators. For residential handler inhalation exposures of any duration, the target MOE is 300. Estimated risks, expressed as MOEs, for all residential handler scenarios are less than 100, and exceed HED's level of concern for short-term dermal exposures. Risk estimates (MOEs) for short-term dermal and inhalation exposures across several homeowner, handler use scenarios can be found in Tables 30(a), 30(b), and 30(c). HED anticipates that aggregating exposures, dermal plus inhalation, from residential handlers would only result in risk estimates that would further exceed HED's level of concern.

A range of application rates were used in the exposure assessments to provide a range of exposure and risk estimates across various residential uses of diazinon. Specifically, the exposure and risk estimates presented in Table 30(a) under the headings "minimum", "typical", and "maximum" are based on an application rate of 0.01, 0.02, and 0.08 lbs ai/gallon, respectively. These application rates are believed to represent the low end of the range of application rates for diazinon products with residential uses, and correspond to labeled rates for wettable powder formulations used on beans, beets and broccoli, i.e., crops with a low exposure potential. In Table 30(b), the exposure and risk estimates presented under the headings "minimum", "typical", and "maximum" are based on an application rate of 0.20, 2.0, and 5.0 lbs ai/gallon (or 0.25, 1.0, and 4.0 lbs ai/acre), respectively. These application rates are believed to represent the highest of the range of application rates for diazinon products with residential uses, and correspond to labeled rates for formulations used in indoor/outdoor environments with a high exposure potential. Table 30(c) provides risk estimates for homeowner handlers applying maximum rates of either the granular (4.4 lb ai/acre) or liquid (4 lb ai/acre) formulations registered for use on turf. These risk estimates are based on data from the registrant's chemical-specific turf transferable residue (TTR) studies (MRID 44959101). Regardless of the application rates used in the exposure assessment, risk estimates expressed as MOEs, for short-term dermal exposure scenarios for residential handlers of diazinon, are all below 100 (<85), and exceed HED's level of concern. If combined, dermal and inhalation exposures would further exceed HED's level of concern. All calculations presented in the tables are based on the following formulas:

*Daily Dermal Dose (mg/kg/day) = {[Unit Exposure (mg/lb ai) * Appl. rate (lb ai/acre or per gallon) * Acres or gallons treated]* 1 (100% dermal absorption correction factor) ÷ 70kg BW}.*

*Daily Inhalation Dose (mg/kg/day) = {[Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion * Application Rate (lb ai/A or per gallon) * Acres or gallons treated /day] ÷ 70kg bw}.*

Table 30a. Residential Handler (exposures are short-term only) MOEs are based on, application rates of "minimum"- 0.01, "typical"- 0.02, and "maximum" -0.08 lbs ai/gallon						
Exposure Scenarios Equipment /Usage	Dermal Baseline ^{ac}			Inhalation Baseline ^{bc}		
	Min.	Typical	Max.	Min.	Typical	Max.
Applying sprays / liquids						
Scenario #1R -Paintbrush	7.6	3.8	0.95	650	320	81
Scenario #2R - Airless Sprayer	1.5	0.74	0.18	15	7.3	1.8
Mixing/loading/applying liquids						

Table 30a. Residential Handler (exposures are short-term only) MOEs are based on, application rates of "minimum"- 0.01, "typical"- 0.02, and "maximum" -0.08 lbs ai/gallon						
Exposure Scenarios Equipment /Usage	Dermal Baseline ^{ac}			Inhalation Baseline ^{bc}		
	Min.	Typical	Max.	Min.	Typical	Max.
<i>Scenario #3R - Low Pressure Handwand</i>	NA	NA	NA	NA	NA	NA
<i>Scenario #4R -Backpack sprayer</i>	NA	NA	NA	NA	NA	NA
<i>Scenario #5R - Garden hose-end sprayer</i>	NA	NA	NA	NA	NA	NA
Loading/applying granules						
<i>Scenario #6R - Belly Grinder</i>	NA	NA	NA	NA	NA	NA
<i>Scenario #7R -Push-type spreader</i>	NA	NA	NA	NA	NA	NA

NA= Not Applicable to this scenario.

^a Baseline dermal unit exposures represent short pants, short sleeved shirt, no gloves, during open mixing/loading, and application..

^b Baseline inhalation unit exposures represent no respirator.

^c Application rates are a range of representative and maximum rates values found in the diazinon labels. The following labels were used to determine the rates:

(1) Wettable powders - EPA Reg. No. 100-460 (Diazinon 50 W). Min. rate represents beans, beets, broccoli, etc. Max. rate represents beans, beets, broccoli, etc.

(2) Liquid formulations - EPA Reg. Nos. 100-784 (AG600 WBC) and 100-461 (AG500 emulsifiable solution). Min. rate represents apricots, beets, etc. Max. rate represents beans, etc. Rights-of-way rate is located on the EPA Reg. No. 100-461.

(3) Granular - EPA Reg. No. 100-469 (Diazinon 14G) and Diazinon Granular Lawn Insect Control (2 percent).

Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern. The granular lawn area is restricted to a maximum of 15,000 ft² (EPA Reg. No. 100-468).

Table 30b. Residential Handler MOEs (exposures are short-term only for dermal plus inhalation exposures, and based on the default acreage = 0.5A, except for granular form'n.)						
Application rates: 0.20 lb ai/gal. (minimum), 2.0 lb ai/gal. (typical), and 5.0 lb ai/gal. (maximum)						
Exposure Scenarios Equipment /Usage	Dermal Baseline ^{ac}			Inhalation Baseline ^{bc}		
	Min.	Typical	Max.	Min.	Typical	Max.
Applying sprays / liquids						
<i>Scenario #1R -Paintbrush</i>	0.38	0.038	0.015	32	3.2	1.3
<i>Scenario #2R - Airless Sprayer</i>	0.074	0.0074	0.003	0.73	0.073	0.029

Table 30b. Residential Handler MOEs (exposures are short-term only for dermal plus inhalation exposures, and based on the default acreage = 0.5A, except for granular form'n.)						
Application rates: 0.20 lb ai/gal. (minimum), 2.0 lb ai/gal. (typical), and 5.0 lb ai/gal. (maximum)						
Exposure Scenarios Equipment /Usage	Dermal Baseline ^{ac}			Inhalation Baseline ^{bc}		
	Min.	Typical	Max.	Min.	Typical	Max.
Mixing/loading/applying liquids						
<i>Scenario #3R - Low Pressure Hand-wand</i>	1.4	0.35	See Table 10(c)	480	120	See Table 10(c)
<i>Scenario #4R -Backpack sprayer</i>	29	7.1	1.8	480	120	30
<i>Scenario #5R - Garden hose-end sprayer</i>	4.7	1.2	See Table 10(c)	1500	380	See Table 10(c)
Loading/applying granules						
<i>Scenario #6R - Belly Grinder</i>	1.9	0.46	See Table 10(c)	340	85	See Table 10(c)
<i>Scenario #7R -Push-type spreader (Head& neck data is not available)</i>	85	17	See Table 10(c)	3300	840	See Table 10(c)

^a Dermal unit exposures represent short pants, short sleeved shirt, no gloves, during open mixing/loading, and application..

^b Inhalation unit exposures represent no respirator.

^c Application rates are a range of representative and maximum rates values found in the diazinon labels. The following labels were used to determine the rates:

(1) Wettable powders - EPA Reg. No. 100-460 (Diazinon 50 W). Min. rate represents beans, beets, broccoli, etc. Max. rate represents beans, beets, broccoli, etc.

(2) Liquid formulations - EPA Reg. Nos. 100-784 (AG600 WBC) and 100-461 (AG500 emulsifiable solution). Min. rate represents apricots, beets, etc. Max. rate represents beans, etc. Rights-of-way rate is located on the EPA Reg. No. 100-461.

(3) Granular - EPA Reg. No. 100-469 (Diazinon 14G) and Diazinon Granular Lawn Insect Control (2 percent).

Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern. The granular lawn area is restricted to a maximum of 15,000 ft² or 0.344 Acres (EPA Reg. No. 100-468), and was used for granular formulation scenarios only.

Application Rates

	Minimum	Typical	Maximum
lb a. i./Acre	0.25	1	4
lb a. i./Gallon	0.20	2	5

Table 30(c). Residential Handler MOEs for Turf Scenarios (short-term dermal and inhalation) [Based on maximum use rates, and 0.3444 acres (15,000 ft ²) MRID No. 449591-01]							
Formulation	Application Rate ¹	Unit Exposure ² (mg/lb ai)		Dose ³ (mg/kg/day)		MOE ⁴	
		dermal	inhalation	dermal	inhalation	dermal	inhalation
Liquid (Low Pressure Hand Wand)	4 lbs. ai/A	100	0.03	2.0	0.00059	0.12	44
Liquid (Garden Hose End Sprayer)	4 lbs. ai/A	30	0.0095	0.59	0.00019	0.42	140
Granular [Push-type Spreader (Head& neck data is not available)]	4 .4 lbs. ai/A	3.0	0.0063	0.065	0.00014	3.9	190
Granular (Belly-Grinder)	4 .4 lbs. ai/A	110	0.062	2.4	0.0013	0.10	20

¹=Application rate is based on the Registrant Study, MRID #449591-01, and the labels, Ortho® Diazinon Ultra™ (EPA Reg # 239-2643, Liquid water base concentrate, 22.4% ai, application rate = 4 lbs. ai/A), Ortho® Diazinon Soil and Turf™ (EPA Reg # 239-2479, granular, 4.84 % ai, application rate = 4.4 lbs. ai/A).

²=Unit Exposure (UE, mg/ lbs. ai handled) is based on short pants, short sleeve shirt, no gloves nor respirator; from SOPs Residential Exposure Assessments Guide (August 1997).

³= Dose = for dermal, {[UE x (Application rate/Acre) x 0.344 Acres]/ Body Weight- 70kg} x 1 (100 % dermal absorption).
for inhalation, {[UE x (Application rate/Acre) x 0.344 Acres]/ Body Weight- 70kg}. The plot areas treated within this study ranged from 1196 ft² to 1472 ft². The area treated in these scenarios, that a resident could treat in a day were assumed to be 15,000 ft² (= 0.3444 Acre), based on the granular label - EPA Reg. No. 100-468.

⁴= Dermal Short-term end point, NOAEL = 0.25 mg/kg/day, MOE = 0.25 mg/kg/day/ Dose (mg/kg/day)
Inhalation, all time periods end point, LOAEL = 0.026 mg/kg/day, MOE = 0.026 mg/kg/day/ Dose (mg/kg/day)

For dermal, MOEs greater than 100, do not exceed HED's level of concern.
For inhalation, MOEs greater than 300, do not exceed HED's level of concern.

(iii). Homeowner Postapplication Exposures and Risk Estimates

Residential uses of diazinon provide opportunities for short-term exposures. Lawn uses provide the opportunity for short-term homeowner handler dermal and inhalation exposures, and short-term postapplication dermal and inhalation exposures to adults and children entering lawn areas after treatment. Indoor crack and crevice treatments, although made by professional applicators, provide opportunities for short-term postapplication dermal and inhalation exposures to adults and children in the home. Several studies were submitted by the registrant for nonoccupational (residential) postapplication exposures. Two of these studies had chemical specific data of sufficient quality to use in risk assessments. Data from these studies were used to assess dermal and inhalation exposures for adults and toddlers: 1) after lawn treatments with liquid and granular formulations of diazinon (MRID 44959101), and 2) after indoor crack and crevice treatments with diazinon (MRID 44348801). Toddlers are the subgroup with the highest potential exposures. All postapplication exposure scenarios were conducted as per HED's Revised Residential Standard Operating Procedures (November 1999).

Lawn Treatments

Tables 31 (a) provides risk estimates (MOEs) for adults and toddlers potentially exposed short-term dermally to diazinon residues through outdoor activities after lawn treatments from liquid or granular formulations. The risk estimates provided in table 31(a) are based on a diazinon-specific turf transferable residue (TTR) study submitted by the registrant (MRID 44959101). Studies were conducted in California (CA), Georgia (GA), and Pennsylvania (PA). The results of these studies categorized as to formulation type used, site, sampling interval, average residue, dose, and MOE are summarized in table 31 (a). This study has been reviewed in detail and this review is contained in Attachment VI. Although supplemental data from other studies were available, the risk estimates are based on MRID 44959101.

In separate studies, TTR residues were sampled less than 4 hours after application at the maximum labeled rate of either the Ortho Diazinon Ultra™ liquid formulation or the Ortho® Diazinon Soil and Turf™ granular formulation without watering the lawn after application (non-irrigated). These samples would result in the worst-case residue concentrations of diazinon on turf. Although the registrant took samples for 8 hours within the study on the day of application, residue levels collected 4 and 8 hours after application were not used in the assessment, because it is assumed that residents may go outside onto their lawns shortly after treatment. Therefore, these risk estimates for dermal exposures after lawn treatments are considered to represent the worst-case scenario.

MOEs for short-term postapplication dermal exposure of adults to diazinon residues on lawns range from 28 to 400 depending on formulation used and site sampled. The MOE based on average residues across all sites for the liquid formulation is 43. The MOE based on average residues across all sites for the granular formulation is 360. All postapplication dermal exposure scenarios based on granular formulations have MOEs greater than 100, and do not exceed HED's level of concern.

MOEs for short-term postapplication dermal exposure of children (toddlers) to diazinon residues on lawns range from 17 to 250 depending on formulation used and site sampled. The MOE based on average residues across all sites for the liquid formulation is 26. The MOE based on average residues across all sites for the granular formulation is 210.

MOEs for the non-dietary oral exposure pathway for children resulting from hand-to-mouth ingestion of diazinon residues range from 420 to 6200 depending on formulation used and site sampled. The MOE based on average residues across all sites for the liquid formulation is 680. The MOE based on

average residues across all sites for the granular formulation is 5600. The MOEs for the non-dietary oral exposure pathway for children resulting from toddler ingestion of grass and granules from diazinon-treated areas was calculated to be 6800 and 260,000, respectively. [See table 31(a) footnotes for calculations.]

The calculations for the dermal and non-dietary, oral exposures include: residue specific data from the diazinon turf transferable residue study, an adult body weight of 70 kg, a child's body weight of 15 kg, transfer coefficients (Tc) of 14,500 cm² /hour for adults and 5200 cm² /hour for children, an exposure duration of 2 hours, 100% dermal absorption, short-sleeved shirt, short pants, and no gloves. For non-dietary hand-to-mouth exposures, the calculations also include: 20 hand-to-mouth events per hour for 2 hours duration, a 20 cm² surface area for a child's 3 fingers inserted into the mouth, and 50% extraction by saliva. The acute oral dietary NOAEL of 0.25 mg/kg/day was the endpoint selected for use in calculating the short-term dermal and oral, non-dietary risk estimates (see table 3). The equations for the calculations are contained in the footnotes following table 31 (a). These defaults (i.e., Tc, events/hr, palm surface areas, body weights, hand-to-mouth events per hour, clothing) used in these assessments and estimates of exposure and risk are from the Revised Standard Operating Procedures for Residential Exposure Assessments Guide (November 1999).

The equations below were used to estimate exposure and risks for short-term dermal and hand-to-mouth exposures in table 31(a). Specific calculations are given in the footnotes to the table.

Dermal Dose (mg/kg/day) = Turf Transferable Residues (TTR) (ug/cm²) x Tc (cm² /hour) x (0.001 mg/μg) x 2 hours/day ÷ Body Weight (kg)

Hand to Mouth Dose (mg/kg/day) = Turf Transferable Residues (TTR) (ug/cm²) x surface area (cm²) x events/hour x (0.001 mg/μg) x 2 hours/day x 0.5% extraction factor from saliva ÷ Body Weight (kg)

Dose from Granule Ingestion (mg/kg/day) = Diazinon ingested (0.3 g /day x 0.0484 % ai) x (0.001 g/mg) ÷ Body Weight (kg)

Dose from Grass ingested = Grass Residue (GR) (ug/cm²) x 25 cm² (amount of grass ingested) x 0.001 mg/ug ÷ Body Weight (kg)

Table 31(a). Nonirrigated Transferable Turf Residues (TTR) for Short-term Dermal Exposure and Risk Estimates									
Location	Formul'n	Sampling Time After Application ¹	Residue ² Average (μg / cm ²)	Dose ³			Short-term MOE ⁴		
				Adult	Child	Child ^a	Adult	Child	Child ^a
GA	Liquid	< 4 hours	0.0053	0.0022	0.0037	0.00014	110	68	1800
	Granular	< 4 hours	0.0019	0.00079	0.0013	0.000051	320	190	4900
CA	Liquid	< 4 hours	0.022	0.0091	0.015	0.00059	28	17	420
	Granular	4-Hours	0.0015	0.00062	0.0010	0.00004	400	250	6200
PA	Liquid	< 4 hours	0.016	0.0066	0.011	0.00043	38	23	580
	Granular	4-Hours	0.0018	0.00075	0.0012	0.000048	330	210	5200

Table 31(a). Nonirrigated Transferable Turf Residues (TTR) for Short-term Dermal Exposure and Risk Estimates									
Location	Formul'n	Sampling Time After Application ¹	Residue ² Average ($\mu\text{g} / \text{cm}^2$)	Dose ³			Short-term MOE ⁴		
				Adult	Child	Child ^a	Adult	Child	Child ^a
Liquid Average	Liquid (All three Sites)	< 4 hours	0.014	0.0058	0.0097	0.00037	43	26	680
Granular Average	Granular (All three Sites)	< 4 hours	0.0017	0.00070	0.0012	0.000045	360	210	5600

¹ = Application rate is based on the Registrant Study, MRID #449591-01, and the labels, Ortho® Diazinon Ultra™ (EPA Reg # 239-2643, Liquid water base concentrate, 22.4% ai, application rate = 4 lbs. ai/A), Ortho® Diazinon Soil and Turf™ (EPA Reg # 239-2479, Granular, 4.84 % ai, application rate = 4.4 lbs. ai/A). Samples were taken from the plots during three sampling time intervals on the day of application (DAT-0) ; they were: Post-app, 4 hours, and then 8 hours.

² = Residue data is based on a diazinon chemical specific Registrant's (Novartis) Study (MRID #449591-01). The highest amount of residues were taken from the day of application (DAT-0), which appears to be within 1-4 hours after application, depending on the formulation.

³ = The highest percentage of residues available from turf, of an application rate of 4 lbs. ai /A, treated with liquid formulated diazinon spray, was 0.05 % (California). Exposure Dose is based on: Short pants, short sleeve shirt, no gloves, Child Body Weight (BW)= 15 kg; Adult BW = 70kg, and 100 % dermal absorption. Turf Transfer Coefficients (Tc), for the Adult = 14,500 and for the Child = 5,200 cm² /hr, and the exposure duration is 2 hours. Dermal Dose = [TTR x Tc x (0.001 mg/ μg) x 2 hours] / BW

⁴ = Dermal Short-term end point and Acute Dietary end point, NOAEL = 0.25 mg/kg/day
MOE = 0.25 mg/kg/day/ Dose (mg/kg/day). Dermal MOEs greater than 100, do not exceed HED's level of concern.

^a = For Non-dietary Hand to Mouth exposure, 20 events per hour x 20 cm² per event (20cm² is based on child's palmer surface area of 3 fingers) and 50% extraction by saliva. Hand to Mouth Dose = [TTR x surface area x events/hr x (0.001 mg/ μg) x 2 hours x 0.5] / BW

Toddler Ingestion of Liquid Diazinon-Treated Turf-grass:

Grass Residues = GR

Highest GR in the above table is 0.022 $\mu\text{g}/\text{cm}^2$,

Dose = [GR x 25 cm² x (0.001 mg/ μg)]/15kg = 0.000037 mg/kg/day;

MOE = 0.25/0.000037=6800

Toddler Ingestion from Granules From Diazinon Treated Areas:

Dose = [0.3 g /day x 0.0484 (% ai) x (0.001 g/mg)]/15kg = 0.00000097 mg/kg/day;

MOE = 0.25/0.00000097= 260,000

This information [defaults (e.g. Tc, events/hr, surface area, etc.)] above is from the Revised SOPs Residential Exposure Assessments Guide (November 1999).

Inhalation exposures after lawn treatments were assessed and risks estimated based on the same study (MRID 44959101) as used for short-term dermal exposure assessments. This study was specifically designed to address toddler inhalation exposures from lawn treatments. However, in addition to the risk estimates for toddlers presented below in Table 31(b), risk estimates for adults based on an overall average exposure have also been provided. Table 31(b) also contains the results of monitoring conducted during the study for airborne residues of diazinon after lawn treatments with the liquid formulation, 22.4% active ingredient (Ortho® Diazinon Ultra™) at the maximum rate of 4 lb ai/acre, and the granular formulation, 4.84% active ingredient (Ortho® Diazinon Soil and Turf™) at the maximum rate of 4.4 lb ai/acre.

Airborne residue samples were taken from the plots within each location during 0 to 2 hours after an application at the maximum label rate, and without irrigation (no watering in of the residues after application). The sampling rate was at 1.5 liters/min. The liquid formulations had the highest airborne residues. Although the registrant took samples for 8 hours within the study on the day of application, residue levels collected 4 and 8 hours after application were not used in the assessment, because it is assumed that residents may go outside onto their lawns shortly after treatment. As in the case of the risk estimates for dermal exposures after lawn treatments, the airborne residue levels measured immediately after application were used to estimate exposures and risks for a worst-case scenario.

Airborne residues were calculated using the following equations:

$$\text{Exposure (mg/day)} = (\mu\text{g}/\text{m}^3) * [8.7 \text{ m}^3/\text{day (default toddler ventilation rate equivalent to 6 liters/minute) or } 15.2 \text{ m}^3/\text{day (default adult ventilation rate equivalent to 10 liters/minute)}] * 1 \text{ (100\% dermal absorption)} * (0.001\text{mg}/\mu\text{g})$$

$$\text{Dose (mg/kg/day)} = \text{Exposure (mg/day)} \div \text{Body weight (kg)}$$

$$\text{MOE} = \text{NOAEL (mg/kg/day)} \div \text{Dose (mg/kg/day)}$$

For adults, short-term inhalation exposure based on an overall average of airborne residues from 3 study sites after application with the liquid and granular formulations result in MOEs of 300 and 3400, respectively.

MOEs for children based on inhalation exposures for the liquid formulation ranged from 65 to 490 depending on the site sampled, and was estimated to be 110 for average residues across sites. MOEs for children based on inhalation exposures for the granular formulation ranged from 700 to 2000 depending on the site sampled, and was estimated to be 2000 for average residues across sites. All postapplication inhalation exposure scenarios based on granular formulations have MOEs for children greater than 700, and do not exceed HED's level of concern.

Combined Exposure and Risk Estimates for Granular Formulations Used on Lawns

Risk estimates from combined dermal and inhalation exposures of adults to diazinon residues after granular applications to lawns result in a risk estimate (ARI) of 2.7, which does not exceed HED's level of concern. Dermal and inhalation exposures of adults to diazinon residues after liquid applications to lawns were not combined because individual dermal exposures exceed HED's level of concern. An ARI of one or greater, does not exceed HED's level of concern.

Combined estimates of exposure for short-term dermal, non-dietary (oral), and inhalation for children after lawn treatments were calculated for exposure scenarios based on the granular formulation. For toddlers, combined short-term dermal and oral, non-dietary exposures (from hand-to-mouth, grass and granule ingestion) result in a MOE of greater than or equal to 200. For toddlers, the inhalation exposure results in a MOE of 1200. Combined dermal, non-dietary (oral), and inhalation exposures of toddlers from granular formulations result in a risk estimate (ARI) equal to 1.3, which does not exceed HED's level of concern. An ARI of one or greater, does not exceed HED's level of concern. Dermal and inhalation exposures of children to diazinon residues after liquid applications to lawns were not combined because individual dermal exposures exceed HED's level of concern. An ARI of one or greater, does not exceed HED's level of concern.

Table 31(b). Short-term Postapplication Inhalation Exposure and Risk Estimates (Data From the Registrant's Study MRID # 449591-01)								
Toddler								
Location	Airborne Levels (0-2 hours after application) ^{1,2} @ 1.5 liters/min (μ g/sample)		Exposure @ 6 liters/min respiration rate (mg/ day)		Dose ³ (mg/kg/day)		MOE ⁴	
	Liquid	Granular	Liquid	Granular	Liquid	Granular	Liquid	Granular
GA	0.20	0.05	0.00080	0.00020	0.000053	0.000013	490	2000
CA	1.5	0.05	0.0060	0.00020	0.0004	0.000013	65	2000
PA	0.99	0.14	0.0040	0.00056	0.00027	0.000037	96	700
Over-all Average for 3 sites	0.90	0.08	0.0036	0.00032	0.00024	0.000021	110	1200
Adult								
Location	Airborne Levels (0-2 hours after application) ^{1,2} @ 1.5 liters/min (μ g/sample)		Exposure @ 10 liters/min respiration rate (mg/day)		Dose ³ (mg/kg/day)		MOE ⁴	
	Liquid	Granular	Liquid	Granular	Liquid	Granular	Liquid	Granular
Over-all Average for 3 sites	0.90	0.08	0.006	0.0054	0.000086	0.0000077	300	3400

¹ = Application rate (4 lbs. ai /A) is based on the Registrant Study, MRID #449591-01, and the labels, Ortho® Diazinon Ultra™ (EPA Reg # 239-2643, Liquid water base concentrate, 22.4% ai, application rate = 4 lbs. ai/A), Ortho® Diazinon Soil and Turf™ (EPA Reg # 239-2479, Granular, 4.84 % ai, application rate = 4.4 lbs. ai/A).

² = Airborne concentration level data is based on a diazinon chemical specific Registrant's (Novartis) Study (MRID #449591-01). The highest non-irrigated, airborne level samples were taken from the plots within each location during 0-2 hours after application (@ 1.5 liters/min). The liquid formulations had the highest airborne levels. Airborne levels (mg/day) = [μ g/sample (is for 2-hrs) x 4 (adjusting up to the default, Toddler ventilation rate of 8.7 m³/day for 24 hours or 6.04 liters/min) x (0.001mg/ μ g)]= mg/day. The Registrant only took samples for only 8-hrs within the study on the day of application (DAT-0). These airborne levels in the table above are the worst case scenario.

³ = The highest percentage of airborne levels, of an application rate of 4 lbs. ai /A, for turf treated with liquid formulated diazinon spray, were for California. Exposure Dose is based on: Short pants, short sleeve shirt, no gloves, and no respirator. Child Body Weight (BW)= 15 kg; Adult BW = 70kg.. An example of Dose calculations, the post-application liquid formulation average airborne level results for toddlers were 0.0036 mg/day, Toddler Inhalation Dose = 0.0036 mg/day / 15 kg =0.00024 mg/kg/day.

⁴ = Inhalation end point for all time periods, LOAEL = 0.026 mg/kg/day. MOE = 0.026 mg/kg/day/ Dose (mg/kg/day).
Toddler MOE = 0.026 mg/kg/day /0.00024 mg/kg/day = 110.

MOEs greater than 300, do not exceed HED's level of concern.

Crack and Crevice Treatments

Crack and crevice treatments, made indoors, with diazinon may result in short-term dermal and inhalation exposures to residues remaining on hard surfaces and in the air after application. Data were submitted, reviewed, and used to assess the inhalation component of this potential exposure (MRID

44348801). The Agency used the data available from MRID 44348801 to estimate inhalation exposure and risk from indoor uses of diazinon. In 1996, the Agency granted a data waiver for indoor residential dermal postapplication exposure data for diazinon. As a result, the submitted data provided information on airborne residues and subsequent inhalation exposures associated with indoor crack and crevice treatment with diazinon, but no data on dermal exposures to diazinon. To assess exposure and estimate risk for short-term postapplication dermal exposures to diazinon in the home, the Agency used the Revised Standard Operating Procedures for Residential Exposure Assessments Guide (November 1999). Estimates of risk for short-term indoor dermal and inhalation exposures were not combined because individual short-term dermal exposures resulted in risk estimates of concern (MOEs less than 100). It is anticipated that combining dermal and inhalation exposures for indoor uses of diazinon will result in risk estimates that further exceed levels of concern.

Table 32(a), below, presents the daily indoor inhalation exposure and risk estimates calculated using the results from three monitoring studies. Two of the studies were conducted by the registrant, and one by North Carolina State University (NCSU). The registrant's studies considered applications to an entire house, while the NCSU study considered treatment to one room only. Airborne residues were measured as 38 ug/m³ immediately after application (0 hour) and declined to 30 ug/m³ 24 hours after application in the NCSU study. Airborne residues were measured as 55 ug/m³ immediately after application (0 hour) and declined to 324ug/m³ 24 hours after application in the Novartis 1980 study. Airborne residues were measured as 69 ug/m³ immediately after application (0 hour) and declined to 11 ug/m³ 24 hours after application in the Novartis 1981 study. These 6 values were averaged to provide an average indoor air concentration of 37.8 µg/m³ over the initial 24 hours after application. (A full review of these data is presented in Attachment VI). According to these monitoring studies, the greatest potential for post application inhalation exposure to diazinon occurs during the 24 hours following the indoor application of diazinon.

To estimate the daily inhaled dose for adults, the Agency used this calculated value of 37.8 µg/m³ as the average indoor air concentration of diazinon during the first 24 hours after indoor application, a default daily inhalation volume of 15.2 m³/day for an adult, 100% dermal absorption, and a 70 kg body weight. To estimate the daily inhaled dose for children, the Agency used this value (37.8 µg/m³) as the indoor air concentration of diazinon during the first 24 hours after indoor application, a default daily inhalation volume of 8.7 m³/day for an adult, 100% dermal absorption, and a 15 kg body weight. The equation used to calculate inhalation dose and MOE is given below:

*Dose (mg/kg/day) = (µg/m³) * [8.7 m³/day (default toddler ventilation rate) or 15.2 m³/day (for adults)] * 1 (100% dermal absorption) * (0.001mg/µg) ÷ Body weight (kg).*

MOE = LOAEL (0.026 mg/kg/day) ÷ Dose (mg/kg/day)

The daily adult inhalation exposure during the first 24 hours postapplication was calculated to be 8.2 µg/kg/day (using 70 kg for body weight and 15.2 m³/day inhalation volume). The daily toddler inhalation exposure during the first 24 hours postapplication was calculated to be 21.9 µg/kg/day (using 15 kg for body weight and 8.7 m³/day inhalation volume). Based on these assumptions, the MOEs for inhalation exposures of adults and children to airborne diazinon residues after crack and crevice treatments are 3.2 and 1.2, respectively. [See table 32(a)].

Using data from the Agency's Nonoccupational Pesticide Exposure Study (NOPES), an average indoor air concentration of 0.32 µg/m³ for Jacksonville, FL in the summertime was estimated. The NOPES data were also used to estimate a 95th percentile concentration of 1.9 µg/m³ for indoor air concentrations in the summertime in Jacksonville. This 95th percentile value represents a reasonable

upper-bound estimate for this geographical area of diazinon air concentration after the initial application. MOEs based on the average inhalation exposure and the 95th percentile exposure as provided by NOPES are 380 and 63, respectively for adults, and 140 and 24, respectively for children. [See table 32 (a) for doses].

Table 32(a). Short-term Postapplication Indoor (crack and Crevice) Inhalation Exposure and Risk Estimates		
Exposure Calculations	Dose Daily Results mg/kg/day	MOEs ¹
From 3-studies above, Daily Adult- First Day (24-hours) After Application	0.0082	3.2
From 3-studies above, Daily Toddler -First Day (24-hours) After Application	0.022	1.2
NOPES -Daily Adult Inhalation Exposure (for the mean and the 95 th percentile)	Mean- 0.000069	380
	95 th - 0.00041	63
NOPES -Daily Toddler Inhalation Exposure (for the mean and the 95 th percentile)	Mean- 0.00019	140
	95 th - 0.001	24

¹ = Margin Of Exposure (MOE) = Inhalation (for all time frequencies) LOAEL (0.026 mg/kg/day)/Daily Inhalation Dose. The Inhalation Target MOE = 300; which does not exceed HED's level of concern.

As stated above, the registrant did not address short-term dermal exposures after crack and crevice treatments during this study. Therefore, data from several sources were examined to complete dermal exposure risk assessments. The data for dermal exposures were obtained from the following sources: the inhalation exposure data (lbs/gms ai applied) from the registrant's study, the current registrant's label- 4E's application rate, current real-estate information (e.g. room sizes within houses, built around 1961 to 1999), and other information (e.g. Tc, events/hr, surface area, etc.) from the Revised SOPs Residential Exposure Assessments Guide, November, 1999. Table 32(b), below, summarizes the short-term dermal exposure, dose, MOEs estimated by the Agency.

Table 32(b). - Short-term Indoor (Crack and Crevice) Postapplication Dermal Exposure and Risk Estimates								
Source (4E-Label) ¹	Application Rate		Area (ft. ²) ²	Indoor Surface Residue (μ g/cm ²) ³	Dose ⁴		MOE ⁵	
	Lbs.	gms.			Adult	Toddler	Adult	Toddler
EPA Reg# 100-463 @ 1%, 1.3 liters ^a	0.026	11.8	Kitchen 40.5 ^a	15.7 (hard surfaces)	15	25	0.017	0.01
EPA Reg# 100-463 @ 1%, 1.3 liters ^b	0.026	11.8	Kitchen 40.5 ^a	15.7 ^a (10% skin contact of hard surfaces)	1.5	2.5	0.17	0.1
EPA Reg# 100-463 @ 0.5%, 1.3 liters ^c	0.013	5.9	Kitchen 40.5 ^a	7.8 (hard surfaces)	7.5	12	0.033	0.021
EPA Reg# 100-463 @ 0.5%, 1.3 liters ^d	0.013	5.9	Kitchen 40.5 ^a	7.8 ^a (10% skin contact of hard surfaces)	0.75	1.2	0.33	0.2
EPA Reg# 100-463 @ 0.5%, 1-gal ^e	0.039	17.7	House 189 ^b	2.6 (carpet surfaces)	5	8.3	0.05	0.03
EPA Reg# 100-463 @ 0.5%, 1-gal ^f	0.039	17.7	House 189 ^b	2.6 ^a (25% skin contact of carpet surfaces)	1.2	2.1	0.21	0.12
EPA Reg# 100-463 @ 0.25%, 1-gal ^g	0.02	8.9	House 189 ^b	1.3 (carpet surfaces)	2.5	4.2	0.1	0.06

Table 32(b). - Short-term Indoor (Crack and Crevice) Postapplication Dermal Exposure and Risk Estimates								
Source (4E-Label) ¹	Application Rate		Area (ft. ²) ²	Indoor Surface Residue ($\mu\text{g}/\text{cm}^2$) ³	Dose ⁴		MOE ⁵	
	Lbs.	gms.			Adult	Toddler	Adult	Toddler
EPA Reg# 100-463 @ 0.25%, 1-gal ^h	0.02	8.9	House 189 ^b	1.3 ^a (25% skin contact of carpet surfaces)	0.62	1	0.40	0.25

¹ = This label was used in the registrant's Study, MRID 443488-01.

^a = This concentration, and amount was approximately used in this study. The predominant area that was treated was in the kitchen (hard surfaces), and air sampling pumps were placed in the kitchen to collect the inhalation exposure data; therefore this dermal exposure/dose corresponds to the inhalation exposure recorded within this study report [see table 32 (c) above (Novartis-1980) for the corresponding inhalation exposure and corresponding dose and MOE].

^b = The same information in foot note ^a above applies, except for assuming only 10 % dermal contact of hard surfaces with residents.

^c = The same information in foot note ^a above applies, except for the concentration; which has been reduced by half to 0.5%.

^d = The same information in foot note ^a above applies, except for assuming only 10 % dermal contact of hard surfaces with residents and the concentration; which has been reduced by half to 0.5%.

^e = This concentration and amount is typical for minor to moderate infestations of insects for an entire house's main living areas, see footnote 2^b, for details of which areas.

^f = This concentration and amount is typical for minor to moderate infestations of insects for an entire house's main living areas (see footnote 2^b, for details of which areas), except for assuming only 25 % dermal contact of carpet surfaces.

^g = This concentration and amount is typical for minor (pest free maintenance) infestations of insects for an entire house's carpeted main living areas (see footnote 2^b, for details of which areas).

^h = This concentration and amount is typical for minor (pest free maintenance) infestations of insects for an entire house's carpeted main living areas (see footnote 2^b, for details of which areas), except for assuming only 25 % dermal contact of treated carpet surfaces.

² = The registrant's study, MRID # 443488-01, did not provide the square footage that was treated by the PCO in both North Carolina studies of 1980 & 1981; nor the area of the kitchens or houses where these studies took place.

^a = For Crack & Crevice application, the average square footage was obtained from real estate data of 6-7 houses, built in 1961 - 1999 and the treated base-board's footage. First, the average estimated potential treated perimeter was determined, for the kitchen; which is: Kitchen = 54 ft. [(14 x 2) + (13 X 2)]. And two, the estimated potential treated base-board footage was determined by assuming the base-board's height is 3.5 inches tall, 2 inches above it and then 3.5 inches out from the wall = 9 inches in all = 0.75ft. The total area treated of the kitchen was determined by taking the total linear feet by the estimated potential treated base-board's footage = 40.5 ft².

^b = For Crack & Crevice application, the average square footage was obtained from real estate data of 6-7 houses, built in 1961 - 1999 and the treated base-board's footage. First, the average estimated potential treated perimeters were determined, and are as follows: Living Rm. = 60 ft. [(17 x 2) + (13 X 2)]; Dining Rm. = 44 ft. [(12 x 2) + (10 X 2)]; Master Bed Rm. = 54 ft. [(15 x 2) + (12 X 2)]; Bed Rm.-2 = 48 ft. [(13 x 2) + (11 X 2)]; and Bed Rm.-3 = 46 ft. [(13 x 2) + (10 X 2)] = total linear feet of 252. And two, the treated base-board footage was determined by the same method as in foot note 2^a. The treated total area of the house was determined by taking the total linear feet by the estimated potential treated base-board's footage = 189 ft².

Only the carpeted main living areas were considered; such as bed rooms, living rooms, and dining rooms, as a screening level to estimate what dermal exposures/doses could be. Hallways, closets, basements, and utility areas were not considered at this time.

³ = Indoor Surface Residue (ISR- $\mu\text{g}/\text{cm}^2$) = [(lbs. ai / square footage area treated) X (50% of potential maximum ai concentration available from crack & crevice treatment) X (% of Indoor surface transferable residues- 5% for carpets, and - 10% for hard surfaces) X (Conversion factor- 4.54 X 10⁸ $\mu\text{g}/\text{lbs}$) X (Conversion Factor- 1.08 X 10⁻³ ft² / cm²)].

⁴ = Dose = [ISR X (Conversion factor- 0.001 mg/ μg) X (Transfer Coefficient-Tc, for adults = 16,700 cm²/hr, and for toddlers = 6,000 cm²/hr) X (Duration, for hard surfaces-4hours, and carpet surfaces-8hours)] / BW, for adults = 70 kg, and for toddlers = 15 kg.

^a = For only 10% dermal contact of treated surfaces, reduce the Tc by 0.1. For only 25% dermal contact of treated surfaces, reduce the Tc by 0.25.

⁵ = MOE = Short-term Dermal NOAEL (0.25 mg/kg/day) / Dermal Dose (mg/kg/day).

(g). Incident Reports

HED concludes that the majority of the reported incidents of acute reactions to diazinon, reported as "poisoning incidents", occur in the home. Incident data taken from the "Review of Diazinon Incident Reports" (HED memorandum from J. Blondell, 7/98 to T. Leighton) are summarized below. Detailed descriptions of 860 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995) constituting the most recent incident information on diazinon poisonings were summarized and reviewed for this risk assessment. These data indicate that in 521 of these cases, diazinon was used alone and was judged to be responsible for the health effects reported. Only cases with a definite, probable, or possible relationship were reviewed. Diazinon ranked 5th as a cause of systemic poisoning in California from 1990 through 1994. Table 32 presents the types of illnesses reported by year.

Table 32. Cases Due to Diazinon Exposure in California Reported by Type of Illness and Year, 1982-1995

Year	Illness Type					
	Systemic ^a	Eye	Skin	Resp	Combina tion ^b	Total
1982	41	7	-	-	-	48
1983	40	8	4	-	-	52
1984	28	7	3	-	-	38
1985	22	5	-	-	1	28
1986	39	5	2	-	-	46
1987	24	6	2	-	-	32
1988	45	6	3	-	-	54
1989	23	6	-	2	-	31
1990	57	4	2	4	1	68
1991	15	4	3	1	2	25
1992	15	3	3	2	1	24
1993	19	4	2	-	-	25
1994	19	3	1	-	-	23
1995	17	4	2	3	1	27
Total	404	72	27	12	6	521

^a Category includes cases where skin, eye, or respiratory effects were also reported.

^b Category includes combined irritative effects to eye, skin, and respiratory system.

Of the total number of diazinon incidents reported (521): 404 persons had systemic illnesses or 77.5% of 521 persons, 72 persons had eye illnesses or 13.8%, and only 5% of the cases involve skin injuries or illnesses.

Nonoccupational categories accounted for just over half of the total cases and 60% of the systemic cases. Thirty percent of the non-occupational cases resulted from residues left from structural applications. By far the majority of these cases occurred when occupants reentered a structure that had just been sprayed. One of the most serious cases of this type involve 35 people who got sick when a carpet was improperly treated. Bystanders were present during the application and affected in at least 20 of these cases. There were even a few cases where the outside of a building was treated and people inside claimed exposure and illness.

Nearly half of the diazinon exposures reported in California involve workers, mostly in agricultural settings. Those who apply diazinon by hand were at greater risk than any other category, accounting for 38% of the occupational categories. This is also the category responsible for over one-half of the adverse effects to the eyes. Drift exposures and persons handling product in transport or in warehouses combined to account for over a quarter of the remaining occupational cases. Detailed review of the occupational cases found that lack of protective equipment was involved in at least 19

incidents. Equipment failure (e.g., hose breaks) was a factor in at least 26 cases. And inadequate precautions when cleaning or maintaining equipment were involved in at least 12 cases. Earlier summaries prepared by California for the years 1975 through 1982 examined all pesticide illnesses involving workers exposed to drift or residue indoors (CDFA 1976-1982). Of the 471 systemic illnesses reported during this six year time period, 123 (26%) were due to diazinon, more than for any other pesticide. In 1979, 57 workers were affected in a single incident when they reentered their offices which had not been adequately ventilated.

A report of all hospitalized cases in California for 1982 through 1994 ranked diazinon first as the leading cause of hospitalization. However, a third of these cases were attempted suicides or homicides. Among the accidental hospitalized cases most occurred among homeowners who misused the product or left it within the reach of very young children. Among the occupational cases that were hospitalized there were four applicators, three of whom were applying the product by hand.

Data from previous years incident reports indicate that diazinon was the 6th leading cause of pesticide related deaths for the years 1961, 1969, 1973, and 1974. Diazinon averaged 2.5 deaths per year during the four survey years and accounted for 3% of the total deaths. Intentional ingestion of diazinon was excluded from these figures. From 1974 to 1976, a sampling of 12% of hospitals nationwide was conducted and revealed that during this period diazinon was estimated to have been the cause of 88 hospitalizations per year and accounted for 3% of the hospitalizations. Of these 88 hospitalizations per year, 12% were related to occupational exposures, 61% to non-occupational and home uses, 24% to intentional ingestion, and 3% from unknown causes.

Another survey of hospitals nationwide conducted from 1977 to 1982 to estimate pesticide related hospitalizations ranked diazinon first in pesticide-related poisoning incidents. Diazinon accounted for 5.6% of the hospitalizations/incidents. Ninety-one percent of the diazinon related exposures requiring hospitalization occurred non-occupationally. A 1984 survey of hospital emergency room cases related to pesticide poisonings indicated that in 2% of the cases diazinon was implicated as the cause, and of the diazinon poisonings reported, 88% of the exposures occurred in the home.

5. Aggregate Exposure and Risk Characterization

Aggregate risk is estimated by combining estimates of dietary (food and water) exposures with estimates of residential use exposures. Diazinon has residential uses and these are included in the aggregate risk assessments as appropriate. When MOEs for multiple exposure pathways differ, but exposures across those pathways must be combined under an aggregate risk assessment, HED uses the Aggregate Risk Index method (ARI method). ARIs greater than 1.0, do not exceed HED's level of concern. Results of the specific aggregate risk assessments included in this document are provided below.

a. Acute Aggregate Exposure and Risk Estimates

The aggregate risk assessment for acute exposures to diazinon includes one-day exposures through food and drinking water, only. Exposure to diazinon from food sources (based on refined exposure estimates) and drinking water (based on surface and ground water monitoring data) do not exceed HED's level of concern for acute dietary risk for any subgroup analyzed. However, if surface water *model* estimates are used in the assessment, risk estimates for infants and children exceed HED's level of concern. HED has indicated that further refinements to sheep commodities (sheep fat and lean meat) in the acute dietary analysis will improve risk estimates. Given the uncertainty in the model and monitoring estimates relative to each other (10x) for surface water concentrations of diazinon, and

therefore, the uncertainty relative to diazinon concentrations in actual drinking water, HED recommends that the acute exposures to diazinon in drinking water be reassessed once surface-water sourced drinking water monitoring data on diazinon become available for use.

b. Short-term Aggregate Exposure and Risk Estimates

HED has concerns for aggregate short-term exposures to diazinon for residential handlers of turf products. Aggregate short-term postapplication exposures to diazinon from granular formulations used to treat lawns do not exceed HED's level of concern. Aggregate short-term postapplication exposures to diazinon for adults and children in the home after indoor crack and crevice treatments exceed HED's level of concern.

Short-term aggregate risk assessments combine short-term residential exposures with average dietary (food and drinking water) exposures. The calculated MOEs for short-term dermal exposures for residential handlers from lawn treatments are less than 85. Inhalation exposures from lawn treatments for residential handlers vary depending on application rates and exposure scenario. However, because all MOEs for dermal exposures of residential handlers are below 100, HED has not aggregated short-term exposures from food, drinking water and residential exposures for handlers. Aggregating additional exposures from food and drinking water with these residential exposures would only result in a risk estimate that would further exceed HED's level of concern. Until residential short-term dermal exposures can be mitigated for residential handlers, aggregate short-term risk estimates for residential handlers exceed HED's levels of concern.

Based on data from chemical-specific studies, postapplication dermal and inhalation exposures (based on residues sampled immediately after application) from indoor crack and crevice treatments result in MOEs less than 100 and 300, respectively. Therefore, HED has not aggregated short-term exposures from food, drinking water with postapplication residential exposures from indoor crack and crevice treatments. Aggregating additional exposures from food and drinking water with these residential exposures would only result in a risk estimate that would further exceed HED's level of concern. Until postapplication residential short-term exposures can be mitigated from indoor treatments, aggregate short-term risk estimates for postapplication exposures to diazinon exceed HED's levels of concern.

Based on data from chemical-specific studies, postapplication dermal and inhalation exposures (based on residues sampled immediately after application) from lawn treatments with liquid formulations of diazinon result in MOEs less than 100 and 300, respectively. Therefore, HED has not aggregated short-term exposures from food, drinking water with postapplication residential exposures from lawn treatments with liquid formulations of diazinon. Aggregating additional exposures from food and drinking water with these residential exposures would only result in a risk estimate that would further exceed HED's level of concern. Until postapplication residential short-term exposures can be mitigated from lawn treatments with liquid formulations of diazinon, aggregate short-term risk estimates for postapplication exposures to diazinon exceed HED's levels of concern.

HED has conducted aggregate risk assessments, combining exposures from food, drinking water, and postapplication residential exposures from lawn treatments with granular formulations of diazinon. Chemical-specific postapplication exposure data are available for the granular lawn treatment scenario. Short-term, aggregate risk estimates for adults combine exposures from food, drinking water, and short-term dermal and inhalation postapplication exposures from granular formulations of diazinon used on lawns. Risk estimates for these short-term aggregate exposures do not exceed HED's level of concern for adults. Short-term aggregate risk estimates for children combine exposures from food, drinking water, and short-term dermal, non-dietary (oral), and inhalation postapplication exposures

from granular formulations of diazinon used on lawns. Risk estimates for these short-term aggregate exposures do not exceed HED's level of concern for children.

The short-term aggregate risk assessment for postapplication exposures from granular formulations of diazinon applied to lawns was accomplished by using the Aggregate Risk Index (ARI) to back-calculate to a theoretical upper limit for diazinon residues in drinking water under a short-term exposure scenario relevant to potential residential exposures to diazinon after lawn treatments in accordance with HED SOP 99.5. The theoretical upper limit in drinking water is referred to as a Drinking Water Level of Comparison (DWLOC) and is based on exposure estimates for adults and children from average residues of diazinon in food, and residues on the lawn after treatment. Estimates of diazinon concentrations in surface water and groundwater from models and monitoring data (as presented earlier in this document) were compared to the DWLOCs calculated for adults and children. If the DWLOC value is greater than the estimated concentrations for diazinon in surface water and groundwater, there is no concern for short-term aggregate exposures to diazinon from the specified lawn treatments with granular formulations. As can be seen in table 33, all calculated DWLOC values for adults and children are greater than the estimated concentrations of diazinon in surface water and ground water. Therefore, for short-term aggregate exposures to diazinon from the specified lawn treatments with granular formulations do not exceed HED's level of concern.

Table 33. Comparison of Aggregate Short-term DWLOC Values to Monitoring and Model Concentration Estimates of Diazinon Concentrations in Surface and Ground Waters ¹					
Population Group	DWLOC (ppb) for Short-Term Assessment	Groundwater (ppb)		Surface water (ppb)	
		monitoring ²	model ³	monitoring	model
Adult (males)	55	0.9	0.80	0.19/0.46	5.8
Adult (females)	47	0.9	0.80	0.19/0.46	5.8
Toddler	8.4	0.9	0.80	0.19/0.46	5.8

¹ DWLOC values are based on average food residues, and short-term dermal, non-dietary (child only), and inhalation exposures to diazinon after lawn treatments with granular formulations.

² A measure of central tendency (mean or median) from monitoring data is appropriate for use chronic aggregate risk assessment. Average (mean) values of diazinon per well were not provided from monitoring data. For the rural well studies, average values determined from all samples analyzed (detects and non-detects) from multiple wells were reported as 0.012 to <0.3 ug/L. EFED provided a 95th percentile concentration value (0.90 ug/L) from all reported maximum values for diazinon in groundwater.

³ SCI-GROW model values are 90-day average concentrations, representing the 99th percentile concentration for pesticides in ground water and are used in acute and chronic assessments for purposes of comparison against the DWLOC values.

The following equations were used to calculate DWLOC values for comparison to model estimates and monitoring data under the short-term aggregate assessment:

$$\text{Aggregate ARI} = \frac{1}{\frac{1}{\text{ARI}_{\text{FOOD}}} + \frac{1}{\text{ARI}_{\text{WATER}}} + \frac{1}{\text{ARI}_{\text{ORAL}}} + \frac{1}{\text{ARI}_{\text{DERMAL}}} + \frac{1}{\text{ARI}_{\text{INHALATION}}}}$$

For adults (males):

Where, $\text{ARI} = [\text{MOE}_{\text{CALCULATED}} \div \text{MOE}_{\text{ACCEPTABLE}}]$.

$ARI_{AGG} = 1$,
 $ARI_{FOOD} = [MOE_{FOOD} \div MOE \text{ (acceptable)}] = [(0.25 \div 1.9 \text{ E-5}) \text{ (mg/kg/day)}] \div 100 = 130$,
 $ARI_{DERMAL} = [MOE_{DERMAL} \div MOE \text{ (acceptable)}] = [(0.25 \div 7.0 \text{ E-4}) \text{ (mg/kg/day)}] \div 100 = 3.6$,
 $ARI_{INHALATION} = [MOE_{INHALATION} \div MOE \text{ (acceptable)}] = [(0.026 \div 7.7 \text{ E-6}) \text{ (mg/kg/day)}] \div 100 = 11.3$, and
 $ARI_{ORAL} =$ not applicable to this risk assessment for adults and the term is removed from the equation.

Substituting the calculated and acceptable MOEs into the equations above and solving for ARI_{WATER} gives:

$ARI_{WATER} = 1.6 = [MOE_{WATER} \div MOE_{ACCEPTABLE}]$; Where the acceptable MOE for water is 100.

$MOE_{WATER} = 1.6 \times 100 = 160$

$160 = \frac{\text{Short-term oral or acute dietary NOAEL}}{\text{Short-term Water Exposure}}$

Short-term Water Exposure (mg/kg/day) = $0.25 \text{ mg/kg/day} \div 160 = 1.5 \text{ E-3 mg/kg/day}$

Substituting the ST Water Exposure value, the Short-term DWLOC for adult males:

$DWLOC(\mu\text{g/L}) = 1.5 \text{ E-3 (mg/kg/day)} \times 70 \text{ (kg)} \div (1\text{E-3 mg}/\mu\text{g}) \times 2 \text{ (L/day)} = 55 \text{ ug/L}$

For adult (females):

Where, $ARI = [MOE_{CALCULATED} \div MOE_{ACCEPTABLE}]$,
 $ARI_{AGG} = 1$,
 $ARI_{FOOD} = [MOE_{FOOD} \div MOE \text{ (acceptable)}] = [(0.25 \div 2.4 \text{ E-5}) \text{ (mg/kg/day)}] \div 100 = 104$,
 $ARI_{DERMAL} = [MOE_{DERMAL} \div MOE \text{ (acceptable)}] = [(0.25 \div 7.0 \text{ E-4}) \text{ (mg/kg/day)}] \div 100 = 3.6$,
 $ARI_{INHALATION} = [MOE_{INHALATION} \div MOE \text{ (acceptable)}] = [(0.026 \div 7.7 \text{ E-6}) \text{ (mg/kg/day)}] \div 100 = 11.3$, and
 $ARI_{ORAL} =$ not applicable to this risk assessment for adults and the term is removed from the equation.

Substituting the calculated and acceptable MOEs into the equations above and solving for ARI_{WATER} gives:

$ARI_{WATER} = 1.6 = [MOE_{WATER} \div MOE_{ACCEPTABLE}]$; Where the acceptable MOE for water is 100.

$MOE_{WATER} = 1.6 \times 100 = 160$

$160 = \frac{\text{Short-term oral or acute dietary NOAEL}}{\text{Short-term Water Exposure}}$

Short-term Water Exposure (mg/kg/day) = $0.25 \text{ mg/kg/day} \div 160 = 1.5 \text{ E-3 mg/kg/day}$

Substituting the ST Water Exposure value, the Short-term DWLOC for adult females:

$DWLOC(\mu\text{g/L}) = 1.5 \text{ E-3 (mg/kg/day)} \times 60 \text{ (kg)} \div (1\text{E-3 mg}/\mu\text{g}) \times 2 \text{ (L/day)} = 47 \text{ ug/L}$

For toddlers:

Where, $ARI = [MOE_{\text{CALCULATED}} \div MOE_{\text{ACCEPTABLE}}]$,

$ARI_{\text{AGG}} = 1$,

$ARI_{\text{FOOD}} = [MOE_{\text{FOOD}} \div MOE \text{ (acceptable)}] = [(0.25 \div 2.7 \text{ E-5}) (\text{mg/kg/day})] \div 100 = 93$,

$ARI_{\text{DERMAL}} = [MOE_{\text{DERMAL}} \div MOE \text{ (acceptable)}] = [(0.25 \div 1.2 \text{ E-3}) (\text{mg/kg/day})] \div 100 = 2.1$,

$ARI_{\text{INHALATION}} = [MOE_{\text{INHALATION}} \div MOE \text{ (acceptable)}] = [(0.026 \div 2.1 \text{ E-5}) (\text{mg/kg/day})] \div 100 = 4.0$, and

$ARI_{\text{ORAL}} = [MOE_{\text{ORAL}} \div MOE \text{ (acceptable)}] = [(0.25 \div 4.5 \text{ E-5}) (\text{mg/kg/day})] \div 100 = 56$

Substituting the calculated and acceptable MOEs into the equations above and solving for ARI_{WATER} gives:

$ARI_{\text{WATER}} = 4.5 = [MOE_{\text{WATER}} \div MOE_{\text{ACCEPTABLE}}]$; Where the acceptable MOE for water is 100.

$MOE_{\text{WATER}} = 4.5 \times 100 = 450$

$450 = \frac{\text{Short-term oral or acute dietary NOAEL}}{\text{Short-term Water Exposure}}$

Short-term Water Exposure (mg/kg/day) = $0.25 \text{ mg/kg/day} \div 450 = 5.6 \text{ E-4 mg/kg/day}$

Substituting the ST Water Exposure value, the Short-term DWLOC for children:

$DWLOC(\mu\text{g/L}) = 5.6 \text{ E-4 (mg/kg/day)} \times 15 \text{ (kg)} \div (1\text{E-3 mg}/\mu\text{g}) \times 1 \text{ (L/day)} = 8.4 \text{ ug/L}$

c. Chronic Aggregate Exposure and Risk Estimates

The aggregate risk assessment for chronic exposures to diazinon includes estimates of average, long-term exposures to diazinon through food and drinking water. Long-term (chronic) exposures are not expected to occur in the home from residential uses of diazinon. Therefore, chronic aggregate risk estimates are the same as those presented for chronic drinking water risks.

Chronic aggregate risk estimates do not exceed HED's level of concern for long-term, average exposures to diazinon in food and groundwater. HED concludes there is no concern for chronic aggregate exposures to diazinon in food and ground-water sourced drinking water.

Chronic aggregate risk estimates based on estimated exposures from food (based on refined exposure estimates) and surface water (based on ambient monitoring data) do not exceed HED's level of concern for chronic aggregate exposures to diazinon in food and surface-water sourced drinking water. However, *model* estimates for concentrations of diazinon in surface water (which are approximately one order of magnitude greater than the concentration estimates from monitoring data) indicate there is a potential concern for infants, children (1 to 6 years old), and females 13+ years old. Given the uncertainty in the model and monitoring estimates relative to each other (10x) for surface water concentrations of diazinon, and the bounding estimates used for long-term exposures to diazinon, and therefore, the uncertainty relative to long-term concentrations of diazinon in actual drinking water, HED recommends that the chronic exposures to diazinon in surface-water-sourced drinking water and chronic aggregate risk be reassessed once surface-water sourced drinking water monitoring data on diazinon become available for use. Appropriate average concentration values can be calculated from the data for use in chronic aggregate risk assessment.

Table 34 provides a comparison of aggregate chronic DWLOC values to selected values from monitoring data and model estimates for groundwater and surface water. A measure of central

tendency (mean or median) from monitoring data is appropriate for use chronic aggregate risk assessment. Average (mean) values of diazinon per well were not provided from groundwater monitoring data. EFED provided a 95th percentile concentration value of 0.90 ug/L (appropriate for acute exposure assessments) from all reported maximum values for diazinon in groundwater. For the rural well studies, average values determined from all samples analyzed (detects and non-detects) from multiple wells were reported as 0.012 to <0.3 ug/L.

Table 34. Comparison of Aggregate Chronic DWLOC Values to Monitoring and Model Concentration Estimates of Diazinon Concentrations in Surface and Ground Waters					
Population Group	DWLOC (ppb) for Chronic Assessment	Groundwater (ppb)		Surface water (ppb)	
		monitoring ¹	model ²	monitoring	model
General U.S.	6.3	0.9	0.80	0.19/0.46	5.8
Non-Hispanic/non-white/non-black	6.0	0.9	0.80	0.19/0.46	5.8
Females (13+ years old)	5.3	0.9	0.80	0.19/0.46	5.8
Infants	2.0	0.9	0.80	0.19/0.46	5.8
Children (1-6 years old)	2.0	0.9	0.80	0.19/0.46	5.8
¹ A measure of central tendency (mean or median) from monitoring data is appropriate for use chronic aggregate risk assessment. Average (mean) values of diazinon per well were not provided from monitoring data. For the rural well studies, average values determined from all samples analyzed (detects and non-detects) from multiple wells were reported as 0.012 to <0.3 ug/L. EFED provided a 95 th percentile concentration value (0.90 ug/L) from all reported maximum values for diazinon in groundwater. ² SCI-GROW model values are 90-day average concentrations, representing the 99 th percentile concentration for pesticides in ground water and are used in acute and chronic assessments for purposes of comparison against the DWLOC values.					

6. Cumulative Risk Assessment

Cumulative risk will be addressed once OPP has finalized its' policies and procedures for conducting a cumulative risk assessment for organophosphates. This is an ongoing effort in OPP.

7. Data Requirements

The following data are required at this time.

Product Chemistry - All pertinent generic data requirements are satisfied for the Novartis and Makhteshim "unstabilized" TGAIs, except that data pertaining to stability (OPPTS 830.6313) are outstanding for the Makhteshim TGAI and data concerning UV/visible absorption for the PAI (OPPTS 830.7050) are required for both TGAIs. All pertinent product-specific data requirements are satisfied for the Novartis 87% FI. Additional product-specific product chemistry data are required for the Prentiss 80%, 50%, 48.7%, 25%, and 10% FIs; the AgrEvo 10% and 5% FIs; and the Makhteshim 92% and 87% FIs. No product chemistry data have been submitted in support of reregistration of the Sureco 70.31%, 25%, and 12.5% FIs and the AgrEvo 25% FI. Data requirements for the repackaged Gowan and Drexel 87% FIs will be satisfied by data for the source products. The product chemistry data requirements for diazinon products are presented in the attached summary tables in the Residue

Chemistry Chapter for diazinon. Refer to these tables for a listing of the outstanding product chemistry data requirements.

Residue Chemistry - Additional residue data are required for beans (lima), blueberries, celery, cucumbers, hops, dried peas (IR-4), spinach, sugar beets, and Swiss chard. Additional residue data on sugar beets reflecting current label rates and PHI are necessary to determine if feed additive tolerances are necessary. Registrant agreed to provide additional data on representative crops from limited rotational crop studies.

Occupational Exposure - The following mixer/loader/applicator data requirements were identified to support reregistration of diazinon:

- 1) Guideline 231 - Estimation of Dermal Exposure at Outdoor Sites (studies are required for handlers in double-layer body protection and chemical-resistant gloves and additional studies are required for handlers using engineering controls.
 - mixing/loading with granulars and emulsifiable concentrates.
 - broadcast and banding application of granulars.
 - application of liquids with various types of equipment (e.g. aerial, airblast, rights-of-way-sprayer, etc.).
- 2) Guideline 232 - Estimation of Inhalation Exposure at Outdoor Sites (studies are required for handlers wearing respirators and additional studies are required for handlers using engineering controls.)
 - mixing/loading with granulars and emulsifiable concentrates.
 - broadcast and banding application of granulars.
 - application of liquids with various types of equipment (e.g. aerial, airblast, rights-of-way-sprayer, etc.).

Based on the use information and data available, the following post-application exposure data are required to support the reregistration of diazinon:

- 1) 132-1(a) foliar dislodgeable residue dissipation (for greenhouse ornamentals),
- 2) 132-1(b) soil residue dissipation,
- 3) 133-3 dermal exposure, and
- 4) 133-4 inhalation exposure: for the uses that may involve greenhouse indoor activities, and human contact with treated soil which include: pre-planting on strawberries, cabbage, turnips, tomatoes, sweet potatoes, radishes, lettuce, cucumbers, etc., and repeated foliar applications within a greenhouses to, ornamental non-flowering plants, ornamental herbaceous plants, ornamental woody shrubs and vines, and all nursery stock. Data are required using both the liquid and granule formulations.
- 5) There are no chemical specific exposure data for handling diazinon treated soil, seed/seedling treatments and sheep treatments; therefore the Agency is requiring data and/or further clarification of the use patterns involving workers handling or working with or in the treated soil, seed/seedling treatments and sheep treatments which may result in post-application exposure. These soil treatment uses are on strawberries, cabbage, turnips, tomatoes, sweet

potatoes, radishes, lettuce, cucumbers, etc.